

OUTBREAKS, ATTACKS, AND ACCIDENTS: COMBATING BIOLOGICAL THREATS

HEARING BEFORE THE SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS OF THE COMMITTEE ON ENERGY AND COMMERCE HOUSE OF REPRESENTATIVES ONE HUNDRED FOURTEENTH CONGRESS SECOND SESSION

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FRIDAY, FEBRUARY 12, 2016

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 9:00 a.m., in room 2123, Rayburn House Office Building, Hon. Tim Murphy (chairman of the subcommittee) presiding.

Members present: Representatives Murphy, Burgess, Blackburn, Griffith, Bucshon, Flores, Brooks, Mullin, Collins, Cramer, Upton (ex officio), DeGette, Castor, Tonko, Kennedy, Green, and Welch.

Also present: Representative Bilirakis.

Staff present: Leighton Brown, Deputy Press Secretary; Rebecca Card, Assistant Press Secretary; Karen Christian, General Counsel; Brittany Havens, Oversight Associate; Charles Ingebretson, Chief Counsel, Oversight and Investigations; Graham Pittman, Legislative Clerk; Chris Santini, Policy Coordinator, Oversight and Investigations; Alan Slobodin, Deputy Chief Counsel, Oversight; Dylan Vorbach, Legislative Clerk; Ryan Gottschall, Democratic GAO Detailee; Christopher Knauer, Democratic Oversight Staff Director; Una Lee, Democratic Chief Oversight Counsel; and Elizabeth Letter, Democratic Professional Staff Member.

Mr. MURPHY. Good morning. We will begin this hearing, to a large extent. We're going to be having votes in a couple hours, so we'll want to make sure we move quickly through this.

Before I start, I want to acknowledge that our good friend and ranking member of the committee, Frank Pallone, is not with us today because his father died. We keep his family in our prayers. And although I did not personally know Frank Pallone, Sr., I know he raised a good son. And so we thank him for that. And we'll continue on from there.

Next, I'm joined today also with my colleague, who is wearing Denver Broncos orange. And congratulations for a Super Bowl. They must be a good team because they beat the Steelers.

Now, on with our hearing.

OPENING STATEMENT OF HON. TIM MURPHY, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

Good morning. We're reminded on a nearly basis that there are those who are seeking to do us harm through a variety of means, including biological attacks. The threats from attack and disease

outbreaks are growing and ever changing, and we are ill prepared to detect and respond to these threats as rapidly needed.

Put simply, we have been caught flatfooted too many times in the past. We face a deadly enemy we cannot see. Our methods to find it are woefully inadequate. And we may not even know it's there until it's too late, and this is frightening. The Federal Government's ambivalence towards biological threats must end.

Today the biological threats confronting the U.S. generally fall into three distinct categories: one, a naturally occurring; two, accidental incidents; and, three, intentional acts which are often associated with acts of terrorism. We must be ready to guard against and respond to each of these threats appropriately.

Now, it's easier for nation-states and terrorists to obtain the resources necessary to produce biological weapons than ever before, and given the ease with which one can obtain and transport these resources, it is difficult for the intelligence community to collect, analyze, and produce intelligence about biological threats. The threat of a biological attack is not as remote as one would hope.

Now, at the same time, pandemic and other highly pathogenic disease are occurring with greater frequency and spreading more quickly throughout the world. As human populations put increasing pressure on remote areas and with ease of global travel, we will see more and more infectious diseases emerge. Since 2002, the world has seen outbreaks of SARS, Chikungunya, cholera, influenza, measles, Ebola, MERS, and now Zika.

The U.S. response to Ebola was a humbling reminder of the adage that everyone has a plan until they are punched in the face. We were not prepared for Ebola, and actions were described with confidence one day and determined to be ineffective the next. This is what shakes the public's confidence, and instead of ensuring that the U.S. had strong central leadership, the administration's answer was to appoint an Ebola czar who served for 3 months.

Sadly, the ad hoc approach continues. A Zika outbreak now threatens the continental U.S. What the world initially thought was a mild illness could in fact have far greater consequences if the virus also brings increases in microencephaly, Guillain-Barre syndrome, eye disorders, and potential for later developmental problems in children.

While the administration has submitted a \$1.8 billion emergency request to combat Zika, its latest budget request continues to leave funding gaps of more than \$1.8 billion in Project BioShield's Special Reserve Fund and pandemic flu countermeasures.

Over the last 3 years, this committee has examined the impacts of and our preparedness for natural and accidental biological incidents. We've held hearings on our flawed response to the Ebola crisis, the need for better preparedness for pandemic and seasonal influenzas, the unsafe practices by the Department of Defense and the Centers for Disease Control on the handling of live anthrax, and the Department of Homeland Security's broken BioWatch system. In the coming weeks we will examine the Federal response to the Zika virus.

Each of these topics has a common denominator: the Federal Government was not adequately prepared. For years, we have lunged from crises to crises, reacting to what just occurred, instead

of planning for the next outbreak or attack. The subcommittee's oversight work has made a difference in each area, but I am very concerned that the Federal Government lacks an overall plan for biodefense. Instead of being reactionary, we must be proactive, with a new approach.

Last fall, the Blue Ribbon Study Panel on Biodefense published its "National Blueprint for Biodefense." The Panel examined the current state of biodefense in the United States, examining issues related to prevention, deterrence, preparedness, detection, and response, to name a few. This is not a book that should sit dusty on a shelf but one that people should read. And I am pleased that two distinguished commission members, Secretary Donna Shalala and former chairman of this subcommittee, Congressman Jim Greenwood, are here today to speak about the important work of this Panel. We thank you.

The Panel's findings that we are, quote, "dangerously vulnerable," unquote, to a biological event because we lack leadership and an overall strategy are frightening. The Panel made 33 recommendations, many which fall within the jurisdiction of the Energy and Commerce Committee and impact work that this subcommittee has done and will continue to do.

The need for improved leadership echoes throughout the Panel's report and is unfortunately a theme we have heard far too often about the Federal Government. Without leadership, there is no coordination of biodefense research, preparedness, and other issues, and without leadership, there is no strategy.

The Panel also makes a number of specific recommendations. We must improve our biosurveillance and biodetection capabilities. We need to detect pathogens in the air in hours and eventually minutes, not days. Agencies already collecting surveillance data should share it, not squirrel it away. We need a platform that allows for rapid diagnostic testing and vaccine development that can be applied not only to the diseases and pathogens we currently know about, but also to the ones we have not yet discovered.

The Energy and Commerce Committee, and this subcommittee in particular, must take the lead in understanding and improving our biodefense capabilities.

I thank our witnesses for being with us today. We look forward to hearing your testimony.

[The prepared statement of Mr. Murphy follows:]

PREPARED STATEMENT OF HON. TIM MURPHY

We are reminded, on nearly a daily basis, that there are those who seek to do us harm through a variety of means, including biological attacks. The threats from attack and disease outbreaks are growing and ever changing, and we are ill prepared to detect and respond to these threats as rapidly as needed. Put simply, we have been caught flat-footed too many times in the past. The Federal Government's ambivalence towards biological threats must end.

Today, the biological threats confronting the U.S. generally fall within three distinct categories: 1, naturally occurring; 2, accidental incidents; and 3, intentional acts, which are often associated with acts of terrorism. We must be ready to guard against and respond to each of these threats.

It is easier for nation-states and terrorists to obtain the resources necessary to produce biological weapons than ever before. And, given the ease with which one can obtain these resources, it is difficult for the intelligence community to collect,

analyze, and produce intelligence about biological threats. The threat of a biological attack is not as remote as one would hope.

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Sadly, the ad hoc approach continues. A Zika outbreak threatens the continental U.S. What the world initially thought was a mild illness could, in fact, have far greater consequences if the virus also brings increases in microcephaly, Guillain-Barre (gee-YAN-buh-RAY) Syndrome, eye disorders, and potential for later developmental problems in children. While the administration has submitted a \$1.8 billion emergency request to combat Zika, its latest budget request continues to leave funding gaps of more than \$1.8 billion in Project Bioshield's Special Reserve Fund and pandemic flu countermeasures.

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Each of these topics has a common denominator—the Federal Government was not adequately prepared. For years, we have lunged from crisis to crisis, reacting to what just occurred instead of planning for the next outbreak or attack. The subcommittee's oversight work has made a difference in each area, but I am very concerned that the Federal Government lacks an overall plan for biodefense. The time for a new approach is long past due. Instead of being reactionary, we must be proactive.

Last fall, the Blue Ribbon Study Panel on Biodefense published its "National Blueprint for Biodefense." The Panel examined the current state of biodefense in the United States, examining issues related to prevention, deterrence, preparedness, detection, and response, to name a few. I am pleased that two very distinguished commission members, Secretary Donna Shalala and the former chairman of this subcommittee, Congressman Jim Greenwood, are here today to speak about the important work of the Panel.

The Panel's findings—that we are "dangerously vulnerable" to a biological event because we lack leadership and an overall strategy—are frightening. The Panel made 33 recommendations, many of which fall within the jurisdiction of the Energy and Commerce Committee and impact work that this subcommittee has done and will continue to do.

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The Energy and Commerce Committee, and this subcommittee in particular, must take the lead in understanding and improving our biodefense capabilities.

Mr. MURPHY. And I now recognize the ranking member of the subcommittee, Ms. DeGette, for 5 minutes.

OPENING STATEMENT OF HON. DIANA DEGETTE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF COLORADO

Ms. DEGETTE. Thank you so much, Mr. Chairman. I too want to welcome our witnesses, in particular former Congressman Greenwood, who sat right there in the chair you're sitting in for many years and who sat next to me while we had a lot of the hearings on these issues that you mentioned in your opening statement today. And I know he's just as frustrated as you and I are about the fact that we still continue to lurch from crisis to crisis in this country without any kind of unified or comprehensive response to some of these issues.

When I was listening to your opening statement, Mr. Chairman, I thought to myself, "Who says bipartisanship is dead?" because my opening statement mirrors your opening statement to the point of talking about some of the very same examples that you discussed. So I won't read the whole opening statement, because I do not subscribe to the adage that everything's been said but it hasn't been said by everybody. So I'll put it into the record. I just want to highlight a couple of the issues.

We've got the Zika virus going on, as you mentioned, right now, and we're scrambling once again after the fact to deploy the appropriate resources to protect our citizens as this spreads. Last year, it was the Ebola outbreak. We did finally organize to respond to that, and we're still trying to put the systems in place to make sure that Ebola doesn't spring up again.

This "National Blueprint for Biodefense" made a number of important findings on how to respond to these natural-occurring threats, but also how to respond to deliberate attack. As you mentioned, Mr. Chairman, the Panel made three dozen recommendations to better posture our Government to respond to these emerging biotreats.

Now, for those of us who were here during the fall of 2001, we remember vividly those little few envelopes of anthrax that arrived on Capitol Hill and the chaos that it caused within the Congress. Offices were closed. Buildings were fumigated. Some congressional business was suspended. Thousands of staffers and Members of Congress lined up to get tested for exposure. And even worse, of course, some of the workers in the postal centers died.

Now, this was a relatively small attack. So imagine what would happen if we had a large attack in a major metropolitan area or someplace else. That's why we have to be organized to deal with these things, and that's what brings us back to the findings of this Panel.

There are a number of really important recommendations, and I recommend to every member of this Panel and every member of the audience that you read the actual blueprint, because it is sobering. But I think that the top observation that's made in this blueprint is that the Nation is underprepared for a bioattack because we still lack centralized biodefense leadership. The Panel recommends appointment of a single national leader under which preparedness for and response to biological threats could be consolidated.

The Panel recommends this authority be institutionalized in the Office of the Vice President of the United States. And what the

Panel says is that this will, quote, “ensure that biodefense will be addressed by every administration at the highest levels with adequate access to the President.” I think this is a very unique recommendation and one that we should explore.

And I just want to say one more thing, Mr. Chairman. One of the grand traditions of the Oversight and Investigation Subcommittee is to shine light on issues like this and to actually move the dialogue forward. So I was really gratified to hear you saying in your opening statement that you don’t just intend to have this hearing today and let this go.

I think if we really have a series of hearings diving deeply into the recommendations of the committee and take their recommendation that we have some of these hearings, we actually can make a long-term difference in how this Nation is prepared. And that may be the very best legacy that not only this Blue Ribbon committee, but also this subcommittee of Energy and Commerce can leave.

With that, I’ll put my full statement in the record, but I’d also like to ask unanimous consent to put Ranking Member Pallone’s full statement in the record due to his inability to be here with his father’s death.

Thank you very much, and I yield back.

Mr. MURPHY. All right. Yes. And I’ll just ask unanimous consent that any other members’ written opening statements be introduced into the record. And without objection, they will be entered.

[The prepared statement of Mr. Pallone follows:]

PREPARED STATEMENT OF HON. FRANK PALLONE, JR.

Thank you for holding this hearing. Combating biological threats is a critical issue that has not been given adequate attention, but I’m hopeful today’s hearing can be another important step towards increasing our Nation’s preparedness.

The Blue Ribbon Panel on Biodefense has conducted a comprehensive review of the Federal Government’s efforts to address the biological threat and identified what remains to be done. Before us today are two distinguished Panel members who are no strangers to this committee: Secretary Shalala, who led the Department of Health and Human Services for 8 years, and Congressman Jim Greenwood, the former chairman of this subcommittee. In addition, I’d like to welcome two individuals who offered their expertise to the Panel: Dr. Tara O’Toole, who served as Undersecretary for Science and Technology at the Department of Homeland Security, and Dr. Gerald Parker, who has provided leadership on these issues at the Departments of Health and Human Services, Homeland Security, and Defense. Thank you to all of our witnesses for being here and for sharing your expertise.

This is not the first high-level commission to examine our Nation’s biodefense preparedness. Experts have repeatedly warned that our ability to respond to biological threats must be improved. However, previous commissions did not produce changes that sufficiently prepared this Nation for the threats that will be discussed today.

That brings us to the Blue Ribbon Study Panel and our hearing today. The Blue Ribbon Panel, following extensive study, has suggested a series of oversight hearings addressing fourteen key areas, many of which fall under this committee’s jurisdiction.

We need to ensure that this Panel’s work does not become yet another undertaking by experts whose recommendations go unanswered. Congressional oversight is key to ensuring that Federal departments and agencies are meeting their mandates and doing so in an effective and efficient way. And therefore, I urge the committee to follow through on the Panel’s recommendations by holding not just this session, but a series of hearings to assess the Nation’s ability to prepare for and respond to biological threats.

I would like to thank our panelists once again for coming and sharing their expertise. I look forward to hearing from each of you about what our Nation can do to improve our biodefense network.

Mr. MURPHY. And I believe, Mr. Chairman, you don't have an opening statement. And, again, given the rush, we want to make sure we hear everything and every member gets a chance to ask questions before votes. We'll just move forward.

So I will introduce the witnesses on the panel for today's hearing. The first witness on today's panel is the Honorable Donna Shalala—welcome here, it is an honor to have you here—former Secretary of Health and Human Services, and here today as a member of the Blue Ribbon Study Panel on Biodefense. Over the course of her career, Secretary Shalala has demonstrated a strong commitment to public service, from the Peace Corps to the Department of Housing and Urban Development. She is a recipient of the Medal of Freedom and currently serves as president and CEO of the Clinton Foundation.

We appreciate your time here today.

Next, my friend and colleague from Pennsylvania, the Honorable Jim Greenwood, former Congressman from the Eighth District of Pennsylvania, chairman of the subcommittee from 2001 to 2004. Mr. Greenwood is also a member of the Blue Ribbon Study Panel on Biodefense and has served since 2005 as president and CEO of the Biotechnology Innovation Organization. In this capacity he has worked with Bio's 1,200 member organizations to aid in the development of biotech solutions to major challenges in agriculture and health care.

And we also look forward to hearing your insights.

Next, Dr. Tara O'Toole, who serves as a senior fellow and executive vice president at In-Q-Tel, a nonprofit strategic investment firm that works to facilitate connection and cooperation between venture-backed technology startups with the U.S. intelligence community. Dr. O'Toole formerly served as Under Secretary of Science and Technology at the Department of Homeland Security and Assistant Secretary for Environmental Health and Safety at the Department of Energy.

I'm looking forward to hearing your expertise today during the hearing, and thank you also for being here.

And now I'll yield to Mr. Flores, who will introduce our next witness from Texas.

Mr. FLORES. Thank you, Mr. Chairman. Also, I thank you for holding this hearing today and for the courtesy of allowing me to introduce one of my classmates and a fellow Texas Aggie and a renowned expert on public health. Dr. Jerry Parker serves as the vice president for public health preparedness and response at the Texas A&M Health Science Center. At Texas A&M he oversees the largest Federal public-private partnership with the Health and Human Services' Biomedical Advanced Research and Development Authority, commonly referred to as BARDA, for vaccine development and manufacture.

Prior to his current role at A&M, Dr. Parker had a distinguished career in public and military service, including serving as a Deputy Assistant Secretary of Defense for Chemical and Biological Defense, and in that position he was responsible for the military's readiness on many of the issues that are before us today. Dr. Parker also served as a Principal Deputy Assistant Secretary in the Office of the Assistant Secretary for Preparedness and Response at

HHS and in a similar role at the Department of Homeland Security.

Again, Mr. Chairman, thank you for allowing me the time to introduce Dr. Parker. His senior leadership positions at the Texas A&M Health Science Center, the Department of Defense, HHS, and DHS are critical to the topic before this committee.

And thank you, Dr. Parker, for being with us today.

I yield back.

Mr. MURPHY. The gentleman yields back. And if there's no more comments, we'll proceed here.

So you're all aware that this committee is holding an investigative hearing and when doing so has had the practice of taking testimony under oath.

Do any of our witnesses have any objections to giving testimony under oath?

Seeing no objections, the Chair then advises you that under the rules of the House and the rules of the committee, you are entitled to be advised by counsel.

Do any of you desire to be advised by counsel during testimony today?

And all the witnesses say no.

In that case, if you would all please rise and raise your right hand, I'll swear you in.

[Witnesses sworn.]

Mr. MURPHY. Thank you. All the witnesses said, "I do."

You are now under oath and subject to the penalties set forth in Title 18, Section 1001 of the United States Code. We will now entertain each of you with a 5-minute summary of your opening statement. We will begin with Ms. Shalala. You're recognized for 5 minutes. Just turn the microphone on and pull it close to you.

STATEMENTS OF DONNA E. SHALALA, PANEL MEMBER, BLUE RIBBON STUDY PANEL ON BIODEFENSE; JAMES C. GREENWOOD, PANEL MEMBER, BLUE RIBBON STUDY PANEL ON BIODEFENSE; TARA O'TOOLE, M.D., EXECUTIVE VICE PRESIDENT, IN-Q-TEL; AND GERALD W. PARKER, JR., D.V.M., ASSOCIATE VICE PRESIDENT, PUBLIC HEALTH PREPAREDNESS AND RESPONSE, TEXAS A&M HEALTH SCIENCE CENTER

STATEMENT OF DONNA E. SHALALA

Ms. SHALALA. Good afternoon, Mr. Chairman, Congresswoman DeGette, and members of the subcommittee. I've submitted a lengthy testimony for the record. Thank you for inviting us here to present our views and recommendations of the bipartisan Blue Ribbon Study Panel on Biodefense. I'm pleased to be joining former Representative Jim Greenwood. We're here on behalf of our co-chairs, former Senator Joe Lieberman and Governor Tom Ridge, and the other members of our Panel, former Senate Majority Leader Tom Daschle and former Homeland Security Advisor Ken Wainstein. It's also good to see Dr. Jerry Parker, who is one of our ex officios, as well as Dr. Tara O'Toole, who constantly advises all of us on this important subject.

We are deeply concerned about the biological threat, whether intentionally induced, naturally occurring, or accidentally released.

And I want to emphasize those three issues, because this is not a report just on intentionally induced biological threat. It also covers the naturally occurring ones or the accidentally released.

I want to take a moment to address the threat now, but let me recommend that you get a classified briefing at your earliest opportunity. Make no mistake, we've been told that our enemies are seriously considering the use of biological weapons. During the invasion of Afghanistan, the United States uncovered evidence that Al Qaeda was trying to develop biological weapons. More recently, ISIL has gained control of enough land, physical infrastructure, scientific expertise, and professional military personnel to potentially create and deploy biological weapons, and they have expressed their intent to use them.

Additionally, the verification protocols associated with the Biological Weapons and Toxin Convention are weak and do not do what the world needs them to do, differentiate between legitimate and malicious activities.

We're equally concerned about the threat of naturally occurring diseases with catastrophic pandemic potential. It's often very difficult for our scientists to guess the correct combination of viruses that will even make up the strain of influenza that will circulate the following year. Nevertheless, diseases do not have to kill millions to produce impact. There are a number of diseases that have affected my own State of Florida and New York and Puerto Rico and the U.S. Virgin Islands and American Samoa over the last 2 years.

Now Zika virus is on the move as well, in some cases resulting in microcephaly in newborns who contract it from their mother. The first case of local transmission has occurred in the United States, in Dallas, which of course was the first city with an Ebola case. This transmission did not occur from mosquitoes. It was sexually transmitted. Imagine the devastating societal consequences if we cannot stop the spread of this disease.

Accidental releases also contribute to biological risk. I'm sure that you're aware of the recent laboratory biosecurity and biosafety mishaps at a number of our high-level laboratories. The organisms in which these laboratories work are too serious, too infectious, and too deadly for us to react indignantly, only to forget after a few months and move on to the next challenge.

Our change must be institutionalized and sustained, and that is our fundamental message today. Our attention span tends to increase and decrease cyclically as different events occur and their impacts fade over time. Since I was Secretary of Health and Human Services, I have seen three administrations increase and decrease their emphasis on biological threats, usually in response to and after recovering from incidents such as the anthrax events of 2001, SARS, H1N1, MERS, and Ebola, and now we're all gearing up again for the Zika virus.

We need a leader at the highest level of Government to take responsibility and develop a comprehensive strategy and a unified budget and lead the whole of the Government, along with non-governmental partners, to improve our national biodefense and to do so attentively and consistently. We recommend that that person be the Vice President of the United States, one of the few who can

get the Government agencies and the nongovernmental partners to work together.

We are not necessarily talking about new programs or funding. Instead, we believe we can build on existing programs and infrastructure. And let me give you a few examples.

We ought to be able to take an environmental biodetection system that was originally designed for the battlefield, for example, evaluate it, and if it seems useful, then modify it to fulfill our needs domestically. We should see how we could build on our pre-existing pervasive and familiar system of community pharmacies to get pharmaceuticals to localities in the midst of a biological incident and maybe create smaller caches in advance. We cannot depend solely on a federally driven public-point-of-dispensing model. Or take our hospitals, which meet accreditation criteria associated with funding provided by the Centers for Medicare and Medicaid Services. We can use that to address various specialties, like trauma, for example.

Doing the same for biodefense would cultivate better hospital preparedness for major infectious disease events. In doing so, we could create a stratified hospital system in advance of a biological event, knowing exactly which facilities are best positioned to handle cases.

The funding that we could get through——

Mr. MURPHY. Ms. Shalala——

Ms. SHALALA [continuing]. Is far greater than what is currently available through the Hospital Preparedness Program. While we support this grant program, it is simply never going to be resourced enough to meet the need.

Mr. MURPHY. Could you just give a wrap-up because you're over a couple minutes. I just want to make sure we have time for everybody.

Ms. SHALALA. I'm closing.

Mr. MURPHY. OK.

Ms. SHALALA. In closing, I just want to note that Congress plays a critical role in providing necessary oversight and legislation. We need all of you to consider these recommendations and, hopefully, to move forward. And now, after you've heard from Jim Greenwood, we'd be happy to answer any questions you have.

[The prepared testimony of Ms. Shalala follows:]

**Hearing of the House Committee on Energy and Commerce
Subcommittee on Oversight and Investigations
"Outbreaks, Attacks, and Accidents: Combating Biological Threats"**

February 12, 2016

**Statement for the Record
The Honorable Donna E. Shalala
Panel Member, Blue Ribbon Study Panel on Biodefense**

Chairman Murphy, Ranking Member DeGette, and Members of the Subcommittee: thank you for inviting us here to present the views and recommendations of the bipartisan Blue Ribbon Study Panel on Biodefense. I am pleased to join my co-panelist, former Representative Jim Greenwood. We are here on behalf of our co-chairs, former Senator Joe Lieberman and Governor Tom Ridge, and the other members of our Panel, former Senate Majority Leader Tom Daschle, and former Homeland Security Advisor Ken Wainstein.

We are here today to discuss the collective findings and concerns of our Study Panel. While we are optimistic that our nation's weaknesses in biodefense can be addressed, we want to convey to you our deep concern about this threat. As you know, naturally occurring and intentionally introduced diseases decimated populations throughout history, and remain among the most dangerous of hazards of the modern world. We are particularly concerned about emerging infectious diseases, and what they mean for the health of Americans and that of the global community. The emergence Chikungunya, an incurable disease that results in paralysis, is striking. Unlike other viruses that have yet to land on our shores, Chikungunya is already here, with thousands of cases in Puerto Rico, Florida, and New York. Zika virus is following a similar progression, beginning in discrete, remote, and tropical locations and then widening its reach. We appreciate the good work this committee has done to assess and mitigate these kinds of

globally emerging infections, with its oversight on disease surveillance, pandemic influenza, and other serious public health issues. We know that you, too, are familiar with the catastrophic potential of highly pathogenic disease and the challenges inherent in managing them.

Infectious diseases impact the security of every American. Yet our Panel found that our attention *to* the threat is not commensurate *with* the threat. We highly recommend that you obtain a classified briefing on the biological threat as soon as possible and get the Intelligence Community's perspective on the potential for biological terrorism and warfare, as well as the national security implications of catastrophic naturally occurring disease events.

While the Clinton Administration paid increased attention to the biological threat, that interest waned prior to the anthrax events of 2001. Letters containing weaponized anthrax closed the Hart Senate Office Building for three months, wreaked havoc with the U.S. Postal Service, reduced business productivity, cost the nation more than one billion dollars by some estimates, and most significantly, took five lives and sickened seventeen more. After those events, Congress and the White House renewed their efforts to improve the nation's biodefense posture. They created new programs, increased laboratory and other needed capacities, developed and stockpiled medical countermeasures (MCM), increased budgets, hired experts, improved protective equipment, re-oriented parts of our intelligence and law enforcement enterprises, and in general, took the threat seriously for a few more years. They lost focus again as years went by without another such attack – despite the fact that criminals continue to commit smaller-scale biocrimes, terrorists groups continue to pursue bioweapons, and emerging infectious diseases continue to march forward. The biological threat is real and present, but our attention span is not.

We are not the first to come before Congress to tell you that the United States is not taking the biological threat seriously enough and that the nation is not preparing sufficiently to deal with a major biological event. The U.S. Commission on National Security/21st Century raised the issue fifteen years ago, the National Commission on Terrorist Attacks upon the United States raised it twelve years ago, the Commission on the Intelligence Capabilities of the United States Regarding Weapons of Mass Destruction raised it eleven years ago, and the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism (WMD Commission) raised it eight years ago. Further, the Intelligence Community states that the biological threat exists and is serious, while simultaneously admitting to weaknesses in its biological collection and analysis activities in this regard.

When we began our work with the Panel in 2014, we wanted to know: (1) if the United States was still vulnerable to the same weaknesses in biodefense that the WMD Commission found in 2008; and (2) what, if anything, we are doing to heed the advice of that Commission and previous panels to take decisive action in defending against biological events of the order that could cause catastrophic loss of life, societal disruption, and loss of confidence in government?

We held public meetings with more than sixty experts (e.g., current and former lawmakers and federal officials, local health department representatives, emergency service providers, academicians, business executives, and other thought leaders). We scrutinized the status of prevention, deterrence, preparedness, detection, response, attribution, recovery, and mitigation. The spectrum of activities that Republican and Democratic Administrations, as well as many policy experts, deem necessary for biodefense. We used this expert input, and conducted

significant additional research, as outlined in the report's Methodology section. We examined the national state of defense against intentionally introduced, accidentally released, and naturally occurring biological threats and released our findings in our bipartisan report, "A National Blueprint for Biodefense: Major Reform Needed to Optimize Efforts," in October 2015.

Our findings were clear. We identified substantial achievements in our capacity to defend against major biological events, but also found serious gaps in biodefense that continue to leave our nation vulnerable. We found that our preparedness is inversely proportional to the severity of the threat, such that the more catastrophic the potential consequences, the less prepared we are.

We also discussed a number of ways we can more effectively address the threat, using resources and infrastructure already have in place. For example, while the Strategic National Stockpile has its role, we also found that community pharmacies (ubiquitous throughout the nation) possess the supply chains, experience with pharmaceutical distribution, and access systems with which the public is already familiar. I believe that these could be used to much greater effect during the response to a biological event and that they may play a significant role in solving the Strategic National Stockpile's inventory management problems. The Institute of Medicine, by mandate of appropriations law, is undertaking a detailed examination of this question and related distribution and dispensing challenges this week.

We believe – as did the WMD Commission before us – that U.S. biodefense lacks a point person. Responsibility for biodefense is one of the federal government's most important functions, with pieces falling within national, homeland, public health, and economic security. As such, it

requires a highly complex and sophisticated enterprise. We have not attained the necessary integration of vision and activity. As a result, the activities we undertake are insufficiently coordinated, collaborative, and innovative. Neither the President nor Congress has charged and authorized an individual to create a cohesive, effective, and efficient whole of the fractionated parts of a dozen departments and agencies responsible for some aspect of biodefense. The last three Presidents appointed special assistants, czars, and others, but jurisdictional and budgetary authorities, guidance, and accountability eluded the individuals holding these positions. We believe that a biodefense leader – and the vision, oversight, and accountability that such an individual brings – could have prevented or mitigated weaknesses in a wide range of activities, including management of the Select Agent Program, implementation of global disease surveillance, and rapid response to public health crises.

Our main recommendation is to install a leader at the highest level of government who recognizes the severity of the biological threat and possesses the authority and political will to defend against it. We recommend that this top-level leader be the Vice President of the United States. The Vice President has a direct line to the President and, when imbued with authority, can act as the President's proxy. The primary goal of centralizing leadership is to place coordination and oversight responsibility in a location with: (1) sufficient jurisdictional and budget authority, regardless of personalities or party in power; and (2) executive decision-making ability. The Vice President possesses these attributes. We also recommend that the Vice President establish and lead a Biodefense Coordination Council, which we envision to be a coalition of public and private sector partners who work together to address biodefense requirements.

(Recommendations 1 and 2)

We provide 33 recommendations in our report, as well as specific short-, medium-, and long-term programmatic, legislative, and policy actions for each of these recommendations. Each of these can improve our Nation's ability to prevent, deter, prepare for, detect, respond to, attribute, recovery from, or mitigate biological events. Together, they comprise a blueprint for biodefense. I would like to highlight three here:

1. **Strategy development:** The nation currently lacks a well-considered and comprehensive biodefense strategy. Our top priority must be to develop the National Biodefense Strategy of the United States of America. This strategy should be all-inclusive and harmonized, identifying all implementation requirements (e.g., Executive Branch organizational structures and requirements, lead and supporting roles, modernization and realignment plans, and dedicated resources). The strategy should also include a mechanism for holding department and agencies accountable for properly executing their responsibilities as leads or participants. We recommend that White House staff collate existing strategies and plans, identify requirements within extant policies, and assess spending history and value. They should then draft a comprehensive strategy that policymakers can use to assess where the nation is falling short of meeting strategic goals and objectives. We also recommend that the President implement a unified biodefense budget. This will allow the President and Congress to determine appropriate resource allocation and conduct oversight systematically. (Recommendation 3)
2. **Hospital preparedness:** Preparedness of our hospitals rises to the fore each time a natural disaster (e.g., Hurricane Katrina) or significant pandemic (e.g., Ebola) occurs. We

want to see more deliberate and systematic planning. We recommend four areas of focus: clinical infection control guidance, tighter management of Hospital Preparedness Program funds, development of incentives for hospitals to prepare by linking incentives to Centers for Medicare and Medicaid Services reimbursement, and establishment of a biodefense hospital system. While these tasks are numerous, a great deal of thinking has been done on how to implement them. It is now time to implement. Some of this will require legislative authority, or at least encouragement, and we ask you to consider moving bills as necessary to achieve these goals. (Recommendations 18-21)

3. **Global health leadership:** While our Panel focuses mostly on domestic policy, we recognize the foreign origins of many emerging diseases, and the impacts that global health has on U.S. health. We further understood that the United States plays an important role in global health security. We, therefore, want to see the United States renew its leadership role in the Biological and Toxin Weapons Convention by strengthening efforts toward implementation, setting goals for the 2016 review conference, and developing actionable recommendations for verification. Secondly, we propose that the United States should lead a new effort to develop a capable global public (and animal) health response apparatus. The World Health Organization is important, but it is equally important to recognize what it does not do. It is not an operational response organization. The United States should convene global health leaders to develop a plan for a new model of response predicated on public-private partnerships. This planning could be achieved through the existing multilateral efforts of the Global Health Security Agenda. (Recommendations 25 and 33).

We believe all of our 33 recommendations are necessary to advance national biodefense and our other recommendations address a variety of additional issues. For example, enhanced intelligence collection, protection of pathogen data and cybersecurity, overhaul of the Select Agent Program, support of hospital preparedness and public health preparedness grants, U.S.-led global health security efforts, and biological weapons prohibition diplomacy will also make us stronger – if executed efficiently, effectively, and in concert.

Congress plays a critical role in conducting necessary oversight and providing needed authorities and funding. Our report provides a number of recommendations to amend legislation and coordinate congressional oversight. In addition, we provide an extensive list of topics that we believe are still in need of oversight, twelve of which we hope you, your colleagues, and the Senate will consider.

Thank you again for the opportunity to appear before you today. We would also like to thank Hudson Institute and the Inter-University Center for Terrorism Studies at Potomac Institute for Policy Studies, our institutional sponsors, and all of the organizations that supported our efforts. We look forward to working with you to strengthen national biodefense.

Please see our bipartisan report, “A National Blueprint for Biodefense: Major Reform Needed to Optimize Efforts” for our 33 recommendations and associated action items.

Recommendations of the Blue Ribbon Study Panel for Biodefense:

1. Institutionalize biodefense in the Office of the Vice President of the United States.
2. Establish a Biodefense Coordination Council at the White House, led by the Vice President.
3. Develop, implement, and update a comprehensive national biodefense strategy.
4. Unify biodefense budgeting.
5. Determine and establish a clear congressional agenda to ensure national biodefense.
6. Improve management of the biological intelligence enterprise.
7. Integrate animal health and One Health approaches into biodefense strategies.
8. Prioritize and align investments in medical countermeasures among all federal stakeholders.
9. Better support and inform decisions based on biological attribution.
10. Establish a national environmental decontamination and remediation capacity.
11. Implement an integrated national biosurveillance capability.
12. Empower non-federal entities to be equal biosurveillance partners.
13. Optimize the National Biosurveillance Integration System.
14. Improve surveillance of and planning for animal and zoonotic outbreaks.
15. Provide emergency service providers with the resources they need to keep themselves and their families safe.
16. Redouble efforts to share information with state, local, territorial, and tribal partners.
17. Fund the Public Health Emergency Preparedness cooperative agreement at no less than authorized levels.

18. Establish and utilize a standard process to develop and issue clinical infection control guidance for biological events.
19. Minimize redirection of Hospital Preparedness Program funds.
20. Provide the financial incentives hospitals need to prepare for biological events.
21. Establish a biodefense hospital system.
22. Develop and implement a Medical Countermeasure Response Framework.
23. Allow for forward deployment of Strategic National Stockpile assets.
24. Harden pathogen and advanced biotechnology information from cyber attacks.
25. Renew U.S. leadership of the Biological and Toxin Weapons Convention.
26. Implement military-civilian collaboration for biodefense.
27. Prioritize innovation over incrementalism in medical countermeasure development.
28. Fully prioritize, fund, and incentivize the medical countermeasure enterprise.
29. Reform Biomedical Advanced Research and Development Authority contracting.
30. Incentivize development of rapid point-of-care diagnostics.
31. Develop a 21st Century-worthy environmental detection system.
32. Review and overhaul the Select Agent Program.
33. Lead the way toward establishing a functional and agile global public health response apparatus.

Mr. MURPHY. Thank you very much.
Mr. Greenwood, you're recognized for 5 minutes.

STATEMENT OF JAMES C. GREENWOOD

Mr. GREENWOOD. Thank you, Mr. Chairman. I'm tempted to ask unanimous consent to insert your opening statement and the opening statement of Ranking Member DeGette as a preface to our report, because it's gratifying to see how aligned you already are with our recommendations.

So thank you for inviting me to discuss preparedness for biological threats on behalf of the bipartisan Blue Ribbon Study Panel on Defense. As the former chair of this subcommittee, I am especially honored to be testifying here today.

The hearing is quite timely, not because a catastrophic biological event has recently occurred, but because one has not occurred on U.S. soil. Whether it's the reintroduction of smallpox by a terrorist, a dirty bomb in an urban center, or another pandemic influenza outbreak, as the Panel notes in our report, we are underprepared to respond to these threats, and we must take immediate steps to be better prepared.

It has been a great privilege to serve on the study panel with my esteemed colleagues. Our report starts from the premise that the biological threat is real and it is growing. While we are better prepared today than we were a decade ago due to Federal and private sector investments, the fact is we are still dramatically underprepared. Our report outlines 33 recommendations. And as Secretary Shalala stated, we as a Panel all strongly support the first recommendation calling for a centralization of leadership over bio-defense in the Office of the Vice President.

I would like to further focus on the recommendations related to strengthening the public-private partnership, as industry plays a key role in protecting our Nation. Consider a company with a novel technology applicable to the biothreats of emerging diseases identified by HHS. This company wants to partner with the Government. But there are so many unique market challenges. Unlike products with a viable commercial market, the market for most medical countermeasures, or MCMs, is defined and supported solely by the Federal Government, making it a major source of research funding and the primary purchaser of vaccines, therapies, and diagnostics against these unique threats.

Many companies begin research at their own risk, conducting R&D even before receiving Federal Government funds. Over the last few years, Government funding for MCM R&D has been decreasing, just as the number of threats have been increasing. The investor community views these products as risky and a distraction from similar products that have a clear commercial value, making it difficult to raise the necessary R&D funds for MCMs in the private capital markets. The regulatory pathway is not always clear.

Lastly, industry has seen a precipitous drop in the level of funds for the purchase of the final MCMs. For many companies the biggest risk is that they will invest significant internal funds and time developing a product only to find there is no clear procurement strategy from the U.S. Government due to sudden shifts in priorities or dearth of funds.

Given all this, we strongly support the need for a comprehensive multiyear strategic plan and unified budget that clearly outlines the priorities for R&D and procurement of medical countermeasures and pandemic influenza products. Such a strategic document would provide much needed transparency on governmental priorities and projected requirements, thus helping companies determine what products to pursue in this partnership.

The MCM enterprise must be fully funded. The Project BioShield Special Reserve Fund, the SRF, was created to provide companies with a guaranteed market for MCMs by establishing a 10-year advanced appropriation of \$5.6 billion. The SRF has indeed proved successful in attracting companies to invest in MCM R&D. Twelve MCMs were procured during a 10-year period, and there are over 200 MCMs in the pipeline.

But the progress made due to Congress' initial \$5.6 billion investment is now in jeopardy. The SRF was reauthorized at \$2.8 billion for fiscal year 2014 through 2018, but rather than a set-aside sum of money, the program has been funded through annual appropriations and much lower than the authorized amount. Unless funding increases, we are risking a \$600 million to a \$1 billion shortfall. Such a sustained deficit endangers the progress we have made and puts the 200 product candidates in the pipeline at risk.

Similarly, pandemic influenza has been woefully underfunded the last few years. Pandemic influenza is a known threat that is very challenging given its versatile and persistent nature. It is imperative that our pandemic preparedness include advanced development of vaccines, antivirals, and diagnostics, rapid response capability building, and the replenishment of vaccine and antiviral stockpiles. Our plan calls for Congress to provide a legislative authorization to define and guide pandemic influenza programs in order to ensure that they receive the funding needed.

Novel incentives could demonstrate the Government's commitment to MCM development. One of the most important incentives in the report is the priority review voucher, the PRV program, for pathogens designated as material threats. The PRV is a proven and valuable incentive that has helped to spur investment in other complex and neglected areas of R&D, such as neglected tropical diseases. An extension of the PRV program to include material threats is viewed by many as a way to offset the dramatic decline in procurement funding for MCMs. Adding MCM targets to the PRV program may help convince investors that the Government is committed to this endeavor and provide increased certainty that MCMs have value.

Improvement must be made in the contracting process as well. In addition to robust sustained funding, the public-private partnership must be strengthened through improvements to the contracting process within BARDA to make it more efficient and predictable. Streamlining is key to ensuring that there are not excessive delays in the implementation of vital research.

I therefore call on Congress to swiftly pass H.R. 3299, the Strengthening Public Health Emergency Response Act of 2015. This bill focuses on many of the issues I've raised today and represents a strong initial step toward implementing the recommendations of the Panel.

This subcommittee plays an integral role through your oversight of Federal biodefense programs. I commend the committee's recent attention to pandemic influenza preparedness and the letters the committee sent to the administration about flu vaccine supply and development and strategic plans. I hope that the Energy and Commerce Committee and this subcommittee continue to exam the issues of biopreparedness further.

The threats facing our Nation are real and many. Having products to support our national preparedness relies on the work of a few dozen biopharmaceutical companies. The only way these companies can continue vital R&D and capacity building is if the U.S. Government demonstrates a strong commitment to them by providing clear priorities, sustained funding, and real incentives. If we invest well now in the broader set of known threats, we will be better prepared to pivot and respond when faced with an unknown threat.

Thank you again for the opportunity to testify on the work of the Blue Ribbon Study commission. I commend the subcommittee for examining the state of our national preparedness for biological threats, and I look forward to your questions.

[The prepared testimony of Mr. Greenwood follows:]

**House Committee on Energy and Commerce
Hearing of the Subcommittee on Oversight and Investigations
"Outbreaks, Attacks, and Accidents: Combating Biological Threats"**

February 12, 2016

**The Honorable James C. Greenwood
Panel Member, Blue Ribbon Study Panel on Biodefense**

Statement for the Record

Chairman Murphy, Ranking Member DeGette, and Members of the Subcommittee:
Thank you for inviting me to discuss preparedness for biological threats on behalf of the bipartisan Blue Ribbon Study Panel on Biodefense. As former Chair of the Energy and Commerce Subcommittee on Oversight and Investigations, I am especially honored to be testifying here today.

This hearing is quite timely. Not because a catastrophic biological event has recently occurred but because one has *not* occurred. The kinds of events we are here to discuss today are health disasters we hope to never see on U.S. soil in our lifetime. Nonetheless, we must be prepared for these types of events. A dirty bomb in an urban center. The dispersion of anthrax in the metro system. The malevolent reintroduction of smallpox. The natural emergence of another Ebola-like disease or another pandemic influenza outbreak. As the Panel notes in our report, we are underprepared to respond to these threats and we must take immediate steps to address these gaps.

For the last year, it has been a privilege to join former Senator Joe Lieberman, former Governor Tom Ridge, former Department of Health and Human Services (HHS) Secretary Donna Shalala, former Senate Majority Leader Tom Daschle, and former Homeland Security Advisor Ken Wainstein on the Study Panel. Our goal was to assess U.S. capabilities with respect to potentially catastrophic biological events and to identify actions to advance our preparedness. We all decided to serve on this Panel, even before the global

events of the Ebola outbreak unfolded, because of concerns that the nation was insufficiently prepared.

Our report, *A National Blueprint for Biodefense: Leadership and Major Reform Needed to Optimize Efforts*, was released in October 2015. The report starts from the premise that the biological threat is real and growing. As you are quite aware, the federal government has undertaken many initiatives – especially since the anthrax attacks of 2001 – to fortify U.S. biodefense capabilities to address this threat. From fielding environmental detection units to stockpiling medical countermeasures (MCMs) to building public health capacity, we are better prepared today than we were a decade ago. But the fact is, we are still dramatically underprepared to respond to a biological event of truly disastrous proportions.

The reason for this is neither lack of interest nor of effort, but a lack of whole-of-government coordination required to achieve this goal. To date, many of the federal activities undertaken to improve our preparedness have been implemented in a strategic vacuum. There is no comprehensive national strategy for biodefense, and no corresponding unified budget for biodefense. As a result, Congress lacks the most important tools it needs for thorough biodefense oversight. Without them, the appropriation of funding for the enterprise is ultimately limited to discrete agency-by-agency visions for expenditures. Further, for biopharmaceutical companies that want to aid in our preparedness, a national strategy and unified budget are vital for defining the research and subsequent funding priorities that industry needs to plan their investments.

Consider a company that has a novel technology that could be applied to the bio-threats or emerging diseases identified by HHS as threats to the U.S. This company wants to partner with the government to address these urgent public health threats but there are so many uncertainties and unique market challenges. Unlike products with a viable commercial market, the market for most MCMs is defined and supported solely by the

federal government. Therefore, the federal government is often the only research funding source **and** the only purchaser of vaccines, therapies and diagnostics against these unique threats. Many companies begin their research at their own risk, conducting early R&D even before receiving government funds in order to better understand the pathogen and the disease. Over the last few years, government funding for R&D has been decreasing, just as the number of threats has been increasing. The investor community views these products as risky and a distraction from similar products that have a clear commercial value, making it almost impossible to raise the necessary R&D funds for MCMs in the private capital markets. The regulatory pathway is not always clear, especially for an emerging infectious disease, and so determining the clinical trial strategy can be complex. Lastly, industry has seen a precipitous drop in the level of funds for *purchase* of the final MCMs. For many companies the biggest risk is that they will invest significant internal funds and time developing a product only to find there is no clear procurement strategy from the U.S. government, foreign governments or non-governmental organizations due to sudden shifts in priorities or a dearth of funds.

Our report outlines 33 recommendations, but today I would like to focus on the recommendations related to strengthening the public-private partnership that supports the development of MCMs (Recommendations 28-29). Congressional leadership could have a powerful impact on the implementation of these recommendations, as well as others.

For example, we recommend that the medical countermeasure enterprise be prioritized, fully funded, and incentivized. As stated above, we strongly support the need for a comprehensive multi-year strategic plan and unified budget that clearly outlines the priorities for research, development and procurement of medical countermeasures, pandemic influenza and emerging infectious diseases. Such a strategic document would provide much needed transparency on government priorities and projected requirements, thus helping companies determine what products to pursue in the partnership. The unified

budget would help support the funding requests necessary for our national and global health security.

The Project BioShield Special Reserve Fund (SRF) was created by Congress in 2004 to provide companies with a guaranteed market for their medical countermeasure products by establishing a ten-year advanced appropriation of \$5.6 billion. Paired with funding for early stage research support from the NIH and the Biomedical Advanced Research and Development Authority (BARDA), the SRF proved successful in attracting companies to invest in MCM R&D. BARDA reports that 12 MCMs against chemical, biological, radiological, and nuclear threats were procured during that ten-year authorization period. There are now more than 200 MCMs in the pipeline and¹ they expect to procure another 12 MCMs by 2018.²

But the progress made due to Congress' initial \$5.6 billion investment is now in jeopardy. The SRF was reauthorized at \$2.8 billion for the period of FY 2014 through 2018, but rather than a set-aside sum of money, the program has been funded through annual appropriations, and funded much lower than the authorization amount. Congress appropriated only \$255 million in both FY 2014 and FY 2015. This year, the funding amount for the SRF was doubled to \$510 million, and industry partners appreciate the commitment to the MCM enterprise that this increase demonstrates, especially in a tough fiscal climate. Unless funding continues to increase, though, we are risking a \$600 million to \$1 billion shortfall below the authorized level. Such a sustained deficit in funding endangers the progress we have made in building up the MCM enterprise and puts the 200 product candidates in the pipeline at risk of never being stockpiled for use in an emergency. I hope that all Members of Congress will make the Special Reserve Fund a priority by supporting its funding throughout the appropriations process each year and exercising oversight to ensure that the program is being funded and administered appropriately.

¹ R. Robinson. BARDA Industry Day, October 2015.

² U.S. HHS PHEMCE. *Multiyear Budget Fiscal Years 2014-2018*.

Similarly, pandemic influenza has been woefully underfunded the last few years considering the threat posed to Americans by this evolving virus year after year. The Centers for Disease Control and Prevention (CDC) estimates that the 2009 H1N1 pandemic infected 43 to 89 million people and killed between 8,000 and 18,000 people.³ Unlike emerging infectious diseases, pandemic influenza is a known threat that is particularly challenging given the dynamic, versatile and persistent nature of these viruses. It is imperative that our pandemic preparedness capabilities keep up with the multiple strains that threaten us each year. Constant vigilance in vaccine development and stockpiling, as well as surveillance, is essential. We must not let the urgent threat of the moment overshadow our efforts to prepare against the long-term and continuous threats from pandemic influenza.

From FY 2004 through FY 2013, pandemic influenza activities at HHS included advanced development of vaccines, antivirals and diagnostics, pre-pandemic rapid response capability building, and the replenishment of pre-pandemic vaccine and antiviral stockpiles. These activities were primarily funded through supplemental appropriations of \$6.23 billion in FY 2006 and \$8.23 billion in FY 2009. It is our understanding that these supplemental balances have been nearly exhausted, yet only \$72 million per year in FY 2015 and FY 2016 has been appropriated. The discrepancy in funding stems, in part, from the fact that pandemic influenza activities at HHS lack an explicit authorization. Recommendation 28 in our plan calls for Congress to provide a legislative authorization to define and guide pandemic influenza programs, in order to ensure that they receive the prioritization and the concomitant funding required to address this urgent and repeated threat.

The Report lists several excellent mechanisms that demonstrate the government's commitment to development and acquisition of MCMs. One of the most important incentives that the U.S. government can use is the priority review voucher (PRV) program

³ Centers for Disease Control and Prevention. Pandemic Flu History. <http://www.flu.gov/pandemic/history/>

for pathogens designated as material threats. The PRV is a proven and valuable incentive that has helped to spur investment in other complex and neglected areas of R&D, such as rare pediatric diseases and neglected tropical diseases. An extension of the PRV program to include material treats is viewed by many companies as a way to offset the dramatic decline in procurement funding for MCMs. Adding MCM targets to the PRV program may help convince investors that the government is committed to this endeavor and provide increased certainty that MCMs can have value in the marketplace.

As we all learned during the recent Ebola outbreak, it is important to invest in MCMs *prior* to an outbreak. When we try to jumpstart R&D efforts while an outbreak is happening, we are already too late. And I would remind this Committee that Ebola had been on the material threat list for many years. The scientific process takes years, often decades, and science can only be sped up so much. So we must make our best attempts to prepare for the broadest possibilities by investing in novel technologies and supporting a strong private sector base in infectious diseases that can assist when needed. While we do not know what disease will emerge next, if we invest well now in the broader set of known threats, we will be better positioned to pivot and respond when faced with an unknown threat.

In addition to robust, sustained funding, the public-private partnership must be strengthened through improvements to the contracting process. Recommendation 29 calls for changes to the contracting process within BARDA to make it more efficient and predictable, as well as for better coordination between the government agencies who are partnering with companies on R&D. Streamlining processes to eliminate unnecessary red tape is key to ensuring that there are not preventable and excessive delays in the implementation of vital research. Furthermore, these reductions would help companies manage their business planning and decrease uncertainty.

While strong leadership is needed from all branches of government, Congress has an important role to play. Congress must exercise its authority on these issues in a more

proactive and coordinated manner. This Subcommittee can play an integral role in this process by exercising additional oversight over federal biodefense programs. I commend the Committee's recent attention to pandemic influenza preparedness and the letters the Committee sent to the Administration last year with questions about flu vaccine supply and development, healthcare system capacities and strategic plans. The Panel proposes a number of Congressional oversight hearings in Appendix A of our report, many of which fall into the Energy and Commerce Committee's jurisdiction, such as examining BARDA's mission space, the development of a unified biodefense strategy for the federal government, bio-surveillance programs, global health response, and MCM innovation, among others. I hope that the Energy and Commerce Committee and this Subcommittee continue to examine the issue of bio-preparedness further.

Finally, I'd like to close by specifically calling for the swift passage of H.R. 3299, the Strengthening Public Health Emergency Response Act of 2015, which has been introduced by Representatives Susan Brooks and Anna Eshoo. Passage of this bill would represent a strong initial step toward implementing the recommendations of the Blue Ribbon Study Panel. The bipartisan bill includes a number of the Panel's recommendations, including streamlining contracting processes, coordinating stockpiling plans, and increasing transparency around future MCM funding needs. H.R. 3299 also addresses our recommendation that the government identify and institute new, meaningful incentives for MCM development. The bill would do so by extending the tropical disease PRV program to biological agents included on the Department of Homeland Security's (DHS's) material threat list. I hope all the members of this Subcommittee will consider cosponsoring this important legislation and actively work to advance it.

The threats facing our nation are real and many. They are splashed across the headlines each day. ISIS has repeatedly threatened the use of biological weapons. In the last year, avian influenza has decimated Midwestern poultry flocks and posed the risk of

infecting humans. And a new infectious disease seems to emerge regularly, whether it is influenza, SARS, MERS, Ebola, chikungunya, or Zika. And we have already had several small-scale targeted attempts such as the 2001 anthrax mailings, which required \$27 million just to decontaminate the Hart Senate Office Building.⁴ Thus far we have been relatively lucky in terms of the impact to our society, economy, and public health, but when something happens on a catastrophic scale, the American public will expect the government to be ready to respond.

The good news is that the domestic policy challenges we face are not insurmountable and correcting these issues will put us on the road for success and accountability. Once the governance structure and the tools are in place, we believe that the entire enterprise will run more smoothly, that gaps will be easier to identify, that capabilities will improve.

Thank you again for the opportunity to testify on the work of the Blue Ribbon Study Panel on Biodefense. I commend the Subcommittee for examining the state of our national preparedness for biological threats. I look forward to your questions.

⁴ U.S. GAO. *Capitol Hill Anthrax Incident: EPA's Cleanup was Successful; Opportunities Exist to Enhance Contract Oversight*. June 2003.

Mr. MURPHY. Thank you, Chairman Greenwood.
And now, Dr. O'Toole, you're recognized for 5 minutes.

STATEMENT OF TARA O'TOOLE

Dr. O'TOOLE. Thank you, Mr. Chairman. I am very happy to be here today to discuss this topic, which has been a preoccupation of mine for most of my professional career. I want to thank you for your kind introduction and emphasize the views I express are my own, not those of In-Q-Tel.

I want to start by congratulating the Blue Ribbon Study Panel on their excellent report, which I hope will be highly influential. I especially endorse and share the Panel's sense of urgency about repairing the country's vulnerability to highly consequential bio-events.

Today, I want to briefly address three issues. First, I want to emphasize the nature and the significance of biological weapons threats and explain why it is a first-tier national security problem.

Secondly, I want to describe why naturally occurring epidemics almost certainly will increase in frequency and impact in the coming years. Natural epidemics, it is important to understand, are different from deliberate bioattacks. The latter would be faster, fiercer, and it may be that many victims are beyond rescue. But if we cannot handle natural outbreaks more effectively and efficiently, we have no defense against biological weapons.

Thirdly, there is a major revolution in our understanding of how the biological world works and our ability to manipulate it. The advances in bioscience and biotechnologies should be part of the foundation of U.S. biodefense against both natural and deliberate epidemics. These advances are going to be extremely beneficial to humankind across many different fields that go beyond biomedicine. But it also means that we now have created a world in which there is wide access to advanced biological knowledge and the materials needed to build and disseminate biological weapons.

As the Defense Science Board said in 2001, an age ago in terms of scientific advances, there are no technical barriers to nonstate actors, including terrorist groups and lone wolves, carrying out devastating bioattacks that could kill millions and cost billions. But these advances in science and in biotechnology also, for the first time, give us powerful tools that could allow us to prevent and to rapidly detect and quench epidemics, whatever their cause. And I'm going to give you some examples of critical technologies which might help realize the Panel's assertion that innovation is a key ingredient and that dramatic improvements in biodefense are within reach.

First of all, the potential destructive power of biological weapons is akin to that of nuclear weapons. In 1993, the Congressional Office of Technology Assessment estimated that a kilogram of aerosolized anthrax dropped on Washington, DC, in ideal weather conditions would result in 1 to 3 million deaths. That's about the same toll as a 1-megaton hydrogen bomb.

These statements are not based on speculation, but on decades of development and field testing by the U.S. military during the Offensive Biological Weapons program of the United States, which was ended by President Nixon in 1969. We also know that the

USSR had a massive secret offensive BW program created after they signed the Biological Weapons Convention in 1972. These were both ambitious, and at least in the case of the U.S., highly successful programs. During the cold war, the U.S. field tested many different bioweapons in realistic conditions, including releases from air, boats, ships, and subways. Declassified U.S. documents from the '60s clearly recognized the strategic power of bioweapons. We do not now know the fate of the Soviet effort.

In the half-century since the U.S. ended its Offensive BW program, there has been a revolution in bioscience. Advances in many fields, including pharmacology and aerosol biological, and our ability to read, write, and edit DNA, the code of life, have resulted in tremendous beneficial achievements. But these advances have also meant the global spread of bioknowledge and access to sophisticated biotechnologies. The materials and know-how needed to build a bioweapon have many legitimate uses. These are dual-use technologies, and as the chairman said, this makes the task of collecting intelligence about covert bioweapons programs exceedingly difficult.

We are going to see an increase in the tempo of naturally occurring epidemics, which we can talk about in the discussion.

I want to end by saying that there are two critical technologies that have not gotten sufficient attention in our biodefense program. The first is rapid diagnostics, upon which we've spent very little money and for which there is a very big market problem that makes it difficult for private companies to pursue diagnostics. And the second is vaccines.

I see that I am out of time, Mr. Chairman, so I will await your questions. Thank you.

[The prepared testimony of Dr. O'Toole follows:]

**U.S. House of Representatives
Committee on Energy and Commerce
Subcommittee on Oversight and Investigations**

***Outbreaks, Attacks and Accidents: Combatting Biological Threats*
February 12, 2016**

Testimony of Tara O'Toole, MD, MPH; Executive Vice President, In-Q-Tel

Introduction

Chairman Murphy, Ranking Member DeGette, and members of the committee, thank you for the opportunity to address the vital issue of the national security threats posed by biological attacks and natural epidemic disease. I am a physician and public health professional. From 2009-13, I served in the Department of Homeland Security as Under Secretary of Science and Technology, and as Assistant Secretary for Environment, Safety and Health in the Department of Energy from 1993-7. In the decade between government positions, I was a Professor of Public Health at Johns Hopkins University and Professor of Medicine and Public Health at the University of Pittsburgh. In each of these positions I helped found and directed university centers devoted to understanding the threat of bioterrorism and of epidemics of infectious disease, and how such events might be prevented or mitigated.

Currently, I am executive vice president at In-Q-Tel, a non-profit organization created by Congress in 1999 that provides the US Intelligence Community with access to innovative small companies in the private sector. My current project focuses on identifying existing and emerging technologies emerging from the life sciences that could significantly improve the nation's ability to rapidly detect and quench destabilizing epidemics, whether natural or engineered.

I wish to congratulate the members and staff of the Blue Ribbon Study Panel on Biodefense for their important – and hopefully highly influential – report, *A National Blueprint for Biodefense*. I especially endorse and share the Panel's sense of urgency about repairing the country's vulnerability to highly consequential bioevents. We have lately been reminded of the potentially devastating effects of natural epidemics and terrible losses and disruption they impose. As the Blue Ribbon Study Panel wrote,

The biological threat has not abated. At some point, we will be attacked with a biological weapon and will certainly be subjected to deadly naturally occurring infectious diseases and accidental exposures, for which our response will be insufficient. There are two reasons for this: 1) lack of appreciation for the extent, severity and reality of the biological threat; and 2) lack of political will. These conditions have reinforced each other.

-*A National Blueprint for Biodefense*, Bipartisan Blue Ribbon Study Panel on Biodefense, October, 2015, p.3

Today, I will address three points:

- 1) The coming decades will include more frequent and more disruptive epidemics due to naturally occurring infectious disease as a result of population and commercial pressures.
- 2) The deliberate use of biological weapons, whether by nation states, terrorist groups or lone wolf actors, represents a strategic threat to US national security. The potential destructive power of bioweapons is equivalent to that of nuclear weapons, and advances in science and technology have removed any technical barriers to building and disseminating highly lethal bioattacks over large areas. Yet, as the Blue Ribbon Panel emphasizes, the U.S. has not moved with determination to reduce our vulnerability to such attacks.
- 3) The “revolution” in biological science and biotechnologies now underway could – with sufficient foresight, imagination and resources - be used to rapidly detect and quench epidemics – whether from natural causes or bioterror. I will suggest some critical technologies which might help realize the Study Panel’s assertions that “dramatic improvements [in biodefense] are within reach”.

The Frequency and Impact of Natural Infectious Disease Outbreaks is Increasing

The world is increasingly likely to face an increasing tempo of epidemics of infectious disease in the 21st century, and these epidemics are more likely to spread quickly and be socially and economically disruptive. As a consequence of expanding populations and commercial pressures causing human intrusion into once remote ecosystems, people have come in contact with new microbes such as Ebola and HIV/AIDS. Two thirds of the more than 30 newly emergent diseases of the past 20 years have been zoonoses – diseases which infect both animals and humans - and the majority of zoonoses arise from wildlife.

Many other factors contribute to the increased risk of epidemics, including the rise of “megacities”, where tens of millions of people live without clean water, basic sanitation or adequate nutrition and in close contact with animals they raise for food or buy in wet markets. Highly interconnected and rapid global patterns of trade and travel also facilitate the spread of disease. SARS, for example, a virus that originates in bats, “jumped” to humans in 2003. A single person infected with SARS transmitted the virus to four others staying in the same Hong Kong hotel. These individuals then traveled to four continents within 24 hours. The total cost of this relatively small epidemic – only 8000 cases occurred worldwide before public health officials halted the outbreak – was estimated to cost the affected regions

about \$60 billion in gross expenditures and business losses over just a single quarter in 2003.

Other infectious disease outbreaks are spread by insects, usually mosquitoes or ticks, as we are witnessing now with the Zika virus outbreak in South America, and as we have seen with mosquito-borne West Nile virus which was discovered in the US in 1999 and is now indigenous across the continent, as well as with Dengue and Chikungunya. Some infectious diseases seem to lie dormant for years, only to “re-emerge”. Others are caused by microbes that mutate into new forms to which humans lack immunity or which are resistant to once useful antibiotics or vaccines. Influenza virus, which continuously mutates, necessitating frequent changes the molecular targets of flu vaccine, is the poster child of viral mutation.

Biological Weapons are a Strategic – and Growing – National Security Threat

There is a long and well documented history of biological weapons use, although it was not until the Cold War that technology enabled the creation of bioweapons with a strategic reach. Both the US and the USSR had ambitious offensive bioweapons programs. President Nixon ended the US program in 1969. The USSR created Biopreparat, a secret, sophisticated, large-scale offensive BW program after signing the Biological Toxins and Weapons Convention in 1972. Details of Biopreparat were revealed by defectors in the 90s, and included the production and stockpiling of *tons* of the bacteria that causes anthrax and smallpox virus, and engineering drug-resistant pathogens. The current status of Russian offensive or defensive bioweapons efforts is unknown, though it does retain closed biology labs under military control.

Although the history of the US offensive bioweapons program is not widely remembered, the program was ambitious and highly successful. During the Cold War, both nations considered aerosolized bioweapons to be adjuncts to nuclear weapons attacks. The US field-tested many different bioweapons in realistic conditions, including releases from air, boats, ships and in subways. Now-declassified documents from the US Department of State written in 1975 recognized the strategic potential and possible terrorist use of these weapons:

“Certain biological agents appear to pose as great a threat to human life as thermonuclear weapons. They appear to be at least as effective and are available to terrorists.”

-Mass Destruction Terrorism Study, Dept. of State, 9/19/75; E.O. 12958, as amended; Declassified 8/10/2010

In 1993, the Congressional Office of Technology Assessment calculated that 100 kilograms of aerosolized anthrax released in Washington, DC under ideal weather conditions would cause approximately as many deaths as a one megaton hydrogen bomb. Common appreciation of the proven destructive power of bioweapons has been warped by the experience of the 2001 anthrax mailings, which employed gram

amounts of anthrax in a very ineffective delivery device. Although the impact of these attacks included 5 deaths and effectively terrorized the nation, the 2001 attacks are not an accurate reflection of the lethality of what was contained in those envelopes.

This is not the place for a detailed examination of the US Offensive Weapons program, but the 25 year history of this program yielded important scientific understanding of bioweapons and their effects. Many important discoveries are not yet integrated into US biodefense plans. For example, a well-prepared bioweapon - using 1960s technologies - would likely deliver a much higher dose of virus or bacteria than would a natural infection, greatly reducing the "incubation" time between exposure and symptoms, and possibly inciting an overwhelming systemic infection that could not be successfully treated with antibiotics. Very high exposure doses might also thwart protection from vaccines, and could alter the manifestation of illness in ways that make clinical diagnosis difficult.

The US and Soviet Cold War, state-sponsored bioweapons programs were ambitious military efforts (Biopreparat employed 50,000 people at its peak), which required significant innovation and experimentation given the era's limited understanding of biological science and biotechnology. Since then, there has been a veritable revolution in our understanding of and ability to manipulate living organisms. These advances have occurred in pursuit of new ways to treat diseases, including the search for new drugs and new ways to deliver them.

As the Defense Science Board reported in 2001, the technical barriers which confronted bioweapons efforts in the 60s no longer pose barriers to terrorist groups mounting large-scale bioattacks:

...Major impediments to the development of biological weapons - strain availability, weaponization technology and delivery technology - have been largely eliminated in the last decade by the rapid, global spread of biotechnology."

- Defense Science Board, *Biological Defense*, June 2001, p.18

But these dual-use technologies have made successful creation and dissemination of a bioattacks by non-state actors far more feasible than was the case in 2001. Advances in pharmacology, in aerosol biology (essential for the protection of crops and for inhalation delivery of drugs), and in our ability to read, write and edit the genetic code - the "code of life" - have resulted in global spread of biological knowledge and the use of biotechnologies.

The materials and know-how needed to build and disseminate a powerful biological weapon are now cheap and widely available in commercial markets. Advances in biotechnology continue to increase accessibility to this knowledge, making assembly and dissemination of such weapons simpler and more fool-proof. As technologies mature, they become more accessible, easier to use. Biological techniques that once

required great skill and effort are now available in handy kits one can buy on the Internet and are used by scientists, technicians and amateur biologists around the world. Moreover, because bioweapons are self-replicating organisms, adversaries could easily develop multiple weapons, increasing the scale or number of attacks.

It is important to recognize that the knowledge and materials needed to build and disseminate a biological attack have many legitimate uses. This makes the task of collecting intelligence about covert biological weapons programs exceedingly difficult, as the Silberman/Robb *Report on Weapons of Mass Destruction Intelligence Capabilities* made clear. Moreover, assigning attribution for bioattacks will be exceedingly difficult unless we catch the perpetrators in the act.

Finally, the burden of defending against bioattacks or natural epidemics falls on the medical and public health communities. These systems are already highly stressed, fragmented, and under resourced, and largely not under federal control. The US lost over 50,000 state public health officials since 2008 as a result of the financial downturn. As we saw with our 2009 experience with H1N1 influenza, and again with last year's Ebola crisis, even the United States has a very limited capacity to make effective vaccines in time to make a difference.

Towards an Effective Biodefense

It is essential that the country become more effective and efficient at preventing, detecting, mitigating and quenching epidemics, whether natural or man-made. The Blue Ribbon Panel on Biodefense makes dozens of recommendations and advocates a more muscular and centralized leadership of US biodefense programs now scattered across multiple federal agencies.

I would like to offer for Congress' consideration, a few suggestions about how we might build a robust biodefense.

Disease Surveillance Requires a Strategy, Rapid Diagnostic Tests, and Sustained Funding

Needed: Strategic Approach to Biosurveillance

The BRP rightly describes surveillance as a "foundational" capability of public health. But "surveillance" is a broad term used to describe many purposes and approaches. Multiple efforts over decades on the part of many smart and dedicated people, and investments of billions of dollars have brought some progress, but have not dramatically improved the nation's ability to see epidemics coming or to attain useful situational awareness once they arrive.

We need to plan and execute a strategic approach to epidemic surveillance that is practical and sustainable and balanced between the need to detect emerging epidemics and predict their course, and the need to provide actionable situational

awareness once epidemics or bioattacks are underway. We should begin with a rigorous examination of why so many surveillance projects have failed or delivered disappointing results – and what has worked.

Pro-MED – Program for Monitoring Emerging Diseases

One bio-surveillance approach, which spotted and warned of several emerging diseases – including SARS, MERS and Zika – before WHO or governments did so, is ProMED, which is a non-profit effort, now supported by the Infectious Disease Society of America, which receives email reports about disease events around the world and posts these messages on email. ProMED has been a uniquely useful surveillance tool, and has repeatedly shown its worth in spite of its small size and lack of complex analytics. It survives on a very small budget which it strains to meet from private donations and other non-profits. The secret sauce of ProMED has been attributed to its network 70 volunteer professionals - physicians, veterinarians, and plant scientists from around the world – who review and monitor incoming messages, using their own networks to deciding what to post and offering added details or explanation. This “human intelligence” helps make ProMED’s reports more trusted - and crucially, *actionable*.

NBIS - the National Biological Integration System

I urge caution before the country invests further in a complex DHS surveillance program called *NBIS – the National Biological Integration System* – that is supported by the Study Panel. NBIS was first conceived over a decade ago, I believe on the basis of erroneous assumptions about the availability and usefulness of digitalized health information, overly optimistic expectations about what data could be collected and analyzed by the federal government and how meaningful such data would be to decision makers. Long experience across the federal government has shown that large, ambitious electronic information systems are difficult to build and often fail. GAO has documented many reasons for these failures, including unclear goals, rapid turnover among inadequately skilled project managers, failure to consult with stakeholders, inadequate funding, etc. I suggest that this program should be part of the strategic review of surveillance programs and should proceed only after we know what, exactly, we are building, how it will work, and who will use it.

OneHealth – Animal and Human Health are Intertwined

As the Study Panel emphasizes, we must do a far better job on surveillance of animals in the wild and in agriculture since the majority of newly emerging diseases originate in animal populations. The likely “hotspots” for spillover of animal diseases into humans are those places where large communities of animals and humans converge: the jungles and forests in tropical zones of Africa, South America and Southeast Asia. Most of our surveillance efforts are, however, focused on temperate zones, and on human disease, so that zoonoses such as SARS, MERS,

Nipah virus, etc. are not recognized until a critical mass of human illness becomes apparent.

Months or even years may pass before animal disease “spills over” into human populations. We should take advantage of this “long fuse” to prepare for oncoming outbreaks – or even better, to stop them. Rapid genomic screening technologies offer new approaches to understanding animal diseases, but field surveillance in general is terribly underfunded, as are established USDA and Dept. of Interior programs for monitoring agricultural and wild animals.

Rapid Diagnostics Tests - Critically Important Tools for Epidemic Control

As we saw with Ebola and are seeing now with Zika, it is very difficult to make sense of what is happening or to control epidemics without rapid diagnostic tests that can distinguish who is truly infected with the pathogen in question - and needs to be isolated or treated - and who is not. Rapid diagnostic tests that can be used in the field or at clinical points of care without requiring elaborate laboratory facilities are an *essential* strategic tool in quenching epidemics.

The lack of such rapid diagnostics greatly increased the toll and duration of the West Africa Ebola epidemic. Our inability to accurately diagnose Zika virus infection is hampering our ability to understand what is happening in South America. We have many innovative technologies for creating new diagnostics, but market forces do not reward investments in this area. The regulatory hurdles for licensing a new diagnostic are sometimes unclear, and as challenging as those for new drug, but diagnostics yield a much smaller return on investment. Plus, current health care billing practices do not value diagnostics. Until the Ebola crisis of last year, BARDA had not invested in diagnostic development. This must change.

I have repeatedly written and testified before Congress on the subject of BioWatch, and would be fairly considered a critic of the program. The governing concept of BioWatch, a collection of environmental sensors located in cities and critical locales across the US and intended to detect specific, aerosolized bioweapons agents, is that detection of airborne agents will enable an earlier “response” to a bioattack and thus save lives. BioWatch was first deployed in 2003, but over the years, questions have been raised as to whether BioWatch detections are reliable and actionable; whether investments in BioWatch sensors are cost-effective or sustainable, and whether BioWatch detections will really speed “response times”. A recent GAO report examines in detail some of the technical problems associated with prototypes of the “next generation” BioWatch technology being funded by DHS. The decade-plus experience with BioWatch operations has also revealed a number of practical, operational and strategic problems with the program that also deserve attention before we embark on a new, expensive and technologically complex surveillance program.

Vaccines are Essential to Epidemic Response

The US should strongly consider pursuing an ambitious strategy to take advantage of recent developments in bioscience to rapidly develop, test and manufacture vaccines against emergent infectious diseases. This would require a consolidated approach to vaccine development and testing, and the engagement of both small innovative companies and big Pharma companies. The US should endeavor to determine the best ways to design vaccines against new pathogens, create efficient safety testing protocols under NIH supervision, and seek to improve the speed and lower the risk of large scale manufacturing.

Vaccines have long been recognized as among the most effective interventions in modern medicine. Vaccines are the most cost-effective and efficacious ways to protect against large, lethal epidemics of infectious disease. An effective vaccine was the key to the eradication of smallpox in 1970.

Bioscience has since generated many new and exciting vaccine technologies - we actually have an “embarrassment of riches” in this field according to Dr. Phil Russell, an eminent vaccine specialist and former head of Walter Reed and the US Army Medical Research Institute for Infectious Diseases. But the country currently has no effective strategy for taking advantage of these new technologies. Vaccines take time to develop, in part because human trials of safety and efficacy are needed before they are used in the field. If they have not been fully tested and are sitting in a stockpile – an expensive business – then they must be manufactured by big drug companies who set aside their business plans to make emergency products or by “warm base” manufacturing plants which are built specifically to “stand ready” to go in times of need – also a very costly proposition.

Many small biotech companies are engaged in this field and eager to help – these companies are scientifically cutting-edge and agile enough to quickly design new approaches to fit emerging problems. But innovative small companies need reliable funding streams to produce their products. They cannot wait for months or years while the government contracting and acquisition system grinds away. Several Ebola vaccines were being slowly advanced over years before the West African crisis – both DOD and HHS were funding such vaccines, but funds were limited, and no human safety testing had occurred when the magnitude of the 2015 crisis became apparent.

Manufacturing vaccines at scale requires the skills and facilities of big pharmaceutical companies such as Merck and Glaxo-SmithKline (GSK), and these companies rather heroically leaped into action to produce enough Ebola vaccine for initial trials and use. HHS, NIAID and FDA as well as the involved companies also performed well once the crisis was upon us. But the process itself was complicated and messy and required a lot of negotiation – among multiple US actors and abroad. We need a much smoother and more understandable and predictable decision

process. Vaccine design and production is one area in which a consolidated US government approach would be valuable. The US government must also establish more predictable, transparent and efficient ways of partnering with the private sector.

The January 1, 2016, cover story of *Science* magazine was titled "Unfilled Vials – Scientifically Feasible Vaccines Against Major Diseases are Stalled for Lack of Funds." Science polled 50 experts who ranked the top 10 vaccines in order of R&D priority based on feasibility and need. There is a broad consensus about which vaccines would work and which would address a pressing public health need. What is missing is a methodical process and funding mechanism from moving these vaccines from "the freezer to the field". A collaboration between government and industry to design, test and stockpile vaccines against the ten pathogens most likely to cause large, lethal epidemics is not a crazy idea. It would cost more than the country has traditionally spent on all of biodefense.

Until we come up with a coherent strategy for rapid design and manufacture of effective vaccines, the US defense against lethal epidemics – both naturally occurring and due to bioterror attacks – will rely mostly on nineteenth century public health methods of contact tracing and isolation. The mortality rate among Ebola victims who made it to modern hospitals and received state-of-the-art supportive care was much lower than the death rate in Africa. In a big epidemic, a very small percentage of Americans will be accommodated in intensive care units. In such a situation, vaccines are the world's best bet. Let's get serious about using American ingenuity to create them.

Today, the digital revolution of the 20th century is converging with extraordinary advances in bioscience to create a "biorevolution" that will have immense benefits for humankind. Bioscience and biotechnology is fueling critically important discoveries in medicine, but biology will also be key to solving many of the major problems confronting us – providing safe and sustainable food supply; enhancing pollution free manufacturing; creating new sources of energy; dealing with an increasingly ageing population. As the *Economist* magazine wrote, "Biology will be to the 21st century what physics was to the 20th." It is past time to use one of the United States' greatest strengths – our ability to innovate – and turn it towards building a robust and enduring biodefense.

Mr. MURPHY. Thank you.
Now we recognize Dr. Parker for 5 minutes.

STATEMENT OF GERALD W. PARKER, JR.

Dr. PARKER. Thank you. Good morning, Chairman Murphy and Ranking Member DeGette. And thank you for the invitation to appear before you today. It is an honor to be here with Secretary Shalala and Congressman Greenwood, who are representing the Blue Ribbon Panel, and Under Secretary O'Toole, who is one of our Nation's highest regarded biodefense leaders.

I put an exclamation point on the bioterror threat. For my part, I've been involved in biodefense since 1982 to the present, from the cold war to the rise of violent extremism, and the rapidly growing risk of naturally occurring transboundary emerging infectious diseases. I have been at the eye of the storm witnessing the evolving biological threat over my career.

Today, I am more concerned than ever about the risk of biological threats, including biological warfare, bioterrorism, and emerging infectious diseases. Biological threats are serious, whether naturally occurring, from an attack, or accidental release. The American public is starting to realize the threat of emerging infectious diseases following Ebola and now presumably Zika. Although the threat of biological warfare, and particularly biological terrorism, is very real too, it is less well understood.

If there's any good news here, the number of countries thought to be conducting some type of illicit biological weapons activity, it has gone down from the end of the cold war from about 12 to 5. But those countries include China, Iran, Russia, Syria, and North Korea, and their operational scenarios for use are no longer limited to military targets.

Today, the risk from a bioterror attack from nonstate actors, violent extremist groups, or individuals on civilian populations is a reality. Biological weapons are sometimes called the poor man's atom bomb, a term first used during the cold war because biological weapons, as we have heard, have the potential to cause mass casualties on the scale of a nuclear weapon. But even a simple bioterror attack, as we heard earlier today, can have devastating consequences, such as occurred from the anthrax letter attacks in 2001 that took 5 lives, sickened 17 more, and over 32,000 people took antibiotics because of potential exposure, and it could have been much worse from that simple attack.

Some question the seriousness of the risk today because further bioattacks have not followed. And fortunately additional attacks have not occurred, which I partially attribute to successful counterterrorism strategies. Why further attacks have not occurred given the relative ease of mounting such an attack, coupled with our vulnerability, is up for debate.

I do not want to overstate and particularly underestimate the threat and risk of a biological attack, and I also cannot predict the future. But we cannot ignore that extremists intend to do us harm by any means, and they are not morally constrained in the methods they use. The intent to acquire and use weapons of mass destruction by the likes of Al Qaeda, ISIL, and others is known. Intelligence gathering is extremely difficult to detect a biological capa-

bility and imminent threat, but we should not take the lack of intelligence as lack of threat. The discovery of an ISIL computer containing plans to develop plague as a bioweapon should give us pause. Just this week the Director of National Intelligence confirmed reports that the Islamic State used a chemical warfare agent in Iraq and Syria.

The Islamic State is growing rapidly, has resources, controls necessary infrastructure and safe havens, and is recruiting scientists that could be capable of developing chemical and biological weapons. It may also be only a matter of time before a biologist becomes a self-inspired violent extremist. We must assume the threat is real and serious.

In addition to bioterror attacks, naturally occurring emerging infectious diseases continue to happen with greater frequency. Pandemic potential influenza viruses, SARS, MERS-CoV, West Nile Virus, Chikungunya, dengue, Ebola, and now Zika are real experiences that tell us we may be on the verge of a global pandemic any time. Our biological threat preparedness response enterprise must also be ready any time.

Biological threats are not new, but we seem to pay attention only when an outbreak occurs or an attack occurs and ignore it between outbreaks. The time between outbreaks, or the interepidemic period, though, is precisely when urgent actions are needed to optimize resources to hone our preparedness and response systems.

Before closing, I would also like to add that initiatives in global health security and One Health are critical too, and they enable work in the prevention side. I would like to thank the members of the subcommittee again for this opportunity, and I'm happy to answer any questions you may have. Thank you.

[The prepared testimony of Dr. Parker follows:]

**Hearing of the House Committee on Energy and Commerce
Subcommittee on Oversight and Investigations**

February 12, 2016

Statement for the Record

Gerald W. Parker, Jr, DVM, PhD

Chairman Murphy, Ranking Member DeGette and Members of the Subcommittee: thank you for inviting me to present at this hearing, Outbreaks, Attacks and Accidents: Combating Biological Threats.

I am honored to testify and share my experience on the evolving biological threat before you today, and to be here with Secretary Shalala and Congressman Greenwood who will report on the Biodefense Blue Ribbon Panel study, “A National Blueprint for Biodefense: Leadership and Reform Needed To Optimize Efforts.” I am also honored to be here with Under Secretary O’Toole, one of the Nation’s highest regarded leaders in biodefense.

For my part, I have been involved in biodefense since 1982 to the present – from the Cold War to the rise of violent extremism; and the rapidly growing risk of naturally occurring, trans-boundary emerging infectious diseases. I have been at the eye of the storm witnessing the evolving biological threat over my career. Today, I am more concerned than ever about the risk of biological threats – including biological warfare, bioterrorism and emerging infectious diseases. Although we are much better prepared today, the recent Ebola response indicates we have a long way to go.

There are three messages that I would like to make to the Committee:

1. Biological Threats are real, and the bioterror threat has the potential to cause mass casualties on a scale similar to a nuclear weapon
2. The inter-epidemic period requires urgent action to optimize available resources and biopreparedness
3. Strong centralized leadership will be necessary to drive urgent action in the inter-epidemic period

In recorded history, communicable diseases decimated populations on many occasions, and nations harnessed their power to create powerful biological weapons in the 20th century. Some in the scientific community once thought that infectious diseases were conquered after the advent of antibiotics and vaccines, such as smallpox and polio vaccines. The global community similarly thought the world would be free of biological weapons after the Biological and Toxins Weapons Convention (BWC) went into force in 1975. Unfortunately, those projections were wrong.

Antimicrobial resistance has emerged rapidly, and newly emerging and reemerging infectious diseases with devastating consequences are the new normal, as we saw last year with Ebola and as we are seeing now with MERS-CoV and, potentially, Zika. Biological weapons development and stockpiling continued even by signatories of the BWC, some on a massive scale such as the former Soviet Union; and biological weapons proliferation continues to be a major concern and threat today. The Department of State assesses that China, Iran, North Korea, Russia and Syria continue to engage in illicit biological weapons activities, and are failing to comply with the BWC.

Biological threats are not new, but we seem to pay attention only when an outbreak or attack occurs, and ignore it between outbreaks. The time between outbreaks - or the inter-epidemic period - is precisely when urgent actions are needed to optimize preparedness and response systems. However, the current strategy appears that we wait for an outbreak to occur before initiating urgent actions, to include providing emergency appropriations instead of taking urgent actions to optimize available resources and improve outcomes during the inter-epidemic period. The current approach is akin to fighting the last outbreak instead of properly preparing for the future one. More importantly, this is the exactly the scenario that the passage of Pandemic and All Hazards Preparedness Act (PAHPA) and the creation of the Biomedical Advanced Research and Development Authority (BARDA) in 2006 was meant to change. Congress did act to create a program to prepare the Nation during this inter-epidemic period, yet we continue to operate in “crisis mode” seemingly every year.

While many hazards plague the modern world, I believe those rooted in modern microbiology are among the most dangerous. I am well aware that your committee must address many issues well beyond this topic, and it can be difficult prioritizing competing demands. But through your work on biodefense and emergency public health preparedness you are well aware of the impact of emerging infectious diseases and bioterror threats. You are also aware that solutions to these threats require a multidisciplinary, integrated team approach through an enterprise that spans national, state, local and tribal governments, as well as industry, academia, other NGOs, families and individuals.

The Evolving Biological Threat: When the BWC went into force in 1975, the capabilities of nation states to develop and stockpile biological weapons were unquestioned. Biological warfare, and now bioterrorism, has the potential to cause mass casualties on the scale of nuclear weapons. Biological weapons, also known as the “poor-man’s atom bomb” are far less costly to produce and the weapon payload – microbial pathogens – are readily available from nature, can be developed in clandestine laboratories with far less technical barriers and delivered by relatively simple and available devices.

The United States engaged in a biological warfare program from 1943 to 1969 not only to develop biological weapons for offensive use, but also to develop countermeasures to defend against the use of biological weapons by the former Soviet Union and other

enemies. The United States terminated the offensive biological weapons program in 1969 largely on moral grounds, and because the use of biological weapons was not the best weapon to achieve tactical military objectives – not because they were not effective strategically.

Recent re-analysis and modeling/simulation of data from technical reports of that era provide new insights on the mass casualty potential of pathogens used as weapons on civilian populations. Today, 4 decades after the BWC went into force, modern biotechnology and molecular biology know-how that was once were the domain of only nation states, is now available to non-state actors and disaffected small groups of scientists around the world, even individual scientists.

In 1995, the citizens of Tokyo and the world were awakened to the reality of chemical terrorism. The Aum Shinrikyo extremist cult in Japan unleashed a crude, but effective sarin chemical weapon on the Tokyo subway system, killing 12 and injuring over a thousand people causing wide spread panic. Law enforcement and other investigators learned after the attack that the Aum Shinrikyo also unsuccessfully attempted anthrax bioterror attacks. Fortunately their bioterror attacks failed, but only because the Aum's biologists selected an avirulent anthrax vaccine strain. Otherwise, there could have been an untold number of anthrax casualties.

On the heels of the Aum Shinrikyo attacks declaring the reality of WMD terrorism and reported proliferation of biological warfare scientific expertise and materials, bioterrorism first became a major national security concern.

Public health authorities similarly became alarmed because local public health would be on the frontline of a bioterror attack in the United States. The laboratory response network, the strategic national stockpile and training on the medical management of biological casualties were established in 1998 that began bioterror preparedness for the civilian population. But, interest quickly waned and concerns were voiced that bioterror preparedness was taking away from day-to-day public health. Progress on bioterror preparedness stalled until the anthrax letter attacks in 2001 in the wake of the tragic events of September 11th that began the era of catastrophic terrorism on the United States Homeland.

The anthrax letter attacks marked the first significant act of bioterrorism in the United States. That attack was one of the easiest bioterror attacks to confront, yet the impact was far reaching. As bad as it was, it could have been much worse had the pathogen involved been a contagious agent, resistant to antibiotics, an unknown pathogen, or delivered in a covert widespread aerosol attack across multiple jurisdictions. As it was, the anthrax letters shut down the Hart Senate Office Building for three months, wreaked havoc with the U.S. Postal Service, reduced business productivity, cost the nation more than one billion dollars, and most importantly, took five lives and sickened seventeen more. More than 30,000 people required post exposure antibiotics and countless more worried well casualties. The medical, public health, law enforcement, and intelligence responses were massive across public and private sectors. Although the

response enterprise worked very hard and with the best available knowledge at the time, serious weaknesses were revealed in almost every aspect of the response.

The Executive and Legislative Branches scrambled to respond and improve the nation's biodefense posture. We created new programs, increased laboratory and other needed capacities, developed and stockpiled medical countermeasures, increased budgets, hired experts, established public health and hospital preparedness programs for infectious disease control and training, re-oriented parts of our intelligence and law enforcement enterprises. In general, we took the threat seriously for a few years and made significant biopreparedness progress. The focus then waned as years went by.

Some question the seriousness of the threat today because further bioattacks have not followed. Fortunately, further attacks have not occurred, which I partially attribute to successful counter terrorism strategies.

Why further attacks have not occurred, given the relative ease of mounting such an attack coupled with our vulnerability is up for debate. I do not want to overstate nor underestimate the threat and risk of a bioterror attack. But, we cannot ignore that violent extremists intend to do us harm by any means, and they are not constrained in the methods they select to use. The intent to acquire and use weapons of mass destruction by the likes of Al Qaeda, the Islamic State of Syria and the Levant (ISIL) and others is known. Intelligence gathering is extremely difficult, particularly for the bioterror threat, but we should not take the lack of tactical intelligence as lack of a threat. It may be that violent extremist groups so far have yet to recruit an individual with the necessary skills, or that a biologist has not become a self inspired violent extremist. We ignore this threat at our peril.

As reported by Rolf Mowatt-Larssen in a study from the Harvard Kennedy School's Belford Center for Science and International Affairs, "The Al Qaeda Weapons of Mass Destruction Threat: Hype of Reality", senior Al Qaeda leadership were committed to acquiring nuclear and biological weapons for their strategic mass casualty potential, and they collaborated with the most senior leaders of other extremist groups indicating that this intent is not limited to just Al Qaeda.

The discovery of an ISIL computer containing plans to develop plague as a bio-weapon underscores this concern. Just yesterday the Director of National Intelligence confirmed reports that the Islamic State used a chemical warfare agent in Iraq and Syria, the first confirmation of such use by an extremist group since the Aum Shinrikyo's attack 20 years ago. The Islamic State is growing rapidly, has resources, necessary infrastructure, controls safe havens, and is apparently recruiting scientists that would be capable of developing chemical and biological weapons. We must assume the threat is real and serious.

There are many reports that have already told us that the United States is not taking the biological threat seriously enough and is unprepared to deal with a catastrophic biological event. The U.S. Commission on National Security/21st Century raised the

issue fifteen years ago, the National Commission on Terrorist Attacks upon the United States raised it twelve years ago, the Commission on the Intelligence Capabilities of the United States Regarding Weapons of Mass Destruction raised it eleven years ago, and the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism (WMD Commission) raised it eight years ago. Further, while the Intelligence Community admits to weaknesses in their biological collection and analysis activities, it does not dispute the fact that the biological threat exists and is serious.

In addition to bioterror attacks, naturally occurring, emerging and reemerging trans-boundary infectious diseases continue along their damaging trajectory. The human immunodeficiency virus, pandemic potential influenza viruses, severe acute respiratory syndrome, middle east respiratory syndrome, west nile virus, chikungunya, dengue, Ebola, and now Zika are real experiences that tell us we may be on the verge of a global pandemic anytime. Our biological threat preparedness enterprise must also be ready anytime.

The need for strong leadership: There is widespread acknowledgement that the global response to Ebola in 2014/2015 was severely deficient. The domestic response to Ebola was unacceptable too, and tells us that despite significant progress – and with the dedicated and untiring work by many in the biopreparedness enterprise – we are still unprepared and have much work to do.

The preparedness and response enterprise goes well beyond public health and includes federal, state, local and tribal governments, as well as industry, academia and other NGOs. It is a vast enterprise that requires complex public-private partnerships to achieve success – and strong leadership.

The Biodefense Blue Ribbon Panel report, “a National Blueprint for Biodefense: Leadership and Major Reform Needed to Optimize Efforts” provides 33 recommendations that spans the framework from threat awareness, prevention and protection, surveillance and detection, response and recovery. But from my view, the Panel’s most important recommendations are the need for strong centralized leadership, coupled to a focused biodefense policy coordinating council and a new biodefense strategy.

This is a much more daunting task than it appears at first glance to establish centralized leadership and a new comprehensive strategy. I have worked in federal interagency coordinating initiatives in the Clinton, Bush and Obama Administrations with many hard working, dedicated colleagues. It is my experience that in the vast interagency process there are many competing demands, and the process itself significantly delays progress. In my opinion, the best model employed to date to harness the vast federal interagency enterprise before an outbreak was the Pandemic Influenza Strategy and Pandemic Implementation Plan that followed the pandemic emergency supplemental appropriation in 2006. Centralized leadership and the implementation plan were the operative components that drove progress with metrics toward positive outcomes. The

implementation plan had over 300 action items and identified lead and supporting department/agencies, as well as called for effective public/private partnerships. Accountability was built into the plan and departments were held accountable for progress. Frankly, some felt this was micromanagement and superseded department/agency authorities, and maybe it did at times. But, the plan enabled the vast enterprise with our private sector and academic partners to make progress that otherwise would not have been possible. This plan also served us very well in the response to the 2009 Influenza Pandemic, where BARDA was able to get every major influenza vaccine maker under contract and producing vaccine in a matter of weeks.

Enhanced intelligence collection, overhaul of the Select Agent Program, hospital preparedness, public health preparedness, laboratory capacities, medical countermeasures development and deployment, and other actions together with U.S.-led international efforts in global health security, and biological weapons prohibition diplomacy will lead us to a position of much greater strength – if executed efficiently, effectively, and in an integrated fashion.

From my experience, I cannot overstate the importance of the Biodefense Blue Ribbon Panel's recommendation on the need for strong centralized leadership, however implemented, and a new biodefense strategy and focused implantation plan. Without this, we will continue to make progress, but incrementally at best and we will not be in a position to drive urgent action during the inter-epidemic period when urgent action is needed the most.

Thank you again for this opportunity to appear before you and share my experiences on this important national security topic.

Mr. MURPHY. I thank you, Dr. Parker, and all the panelists. It's pretty sobering testimony we hear. So let me start off and recognize myself for 5 minutes.

First, Dr. O'Toole, you refer to this as a first-tier national security problem and that bioattacks are faster and fiercer. So it seems like these natural outbreaks, they really are test runs for prevention. How we handled Ebola, how we handled SARS, how we will handle the Zika virus gives us an opportunity to work on prevention, detection, and responding. But I don't think we are at all where we need to be. So given that, is there reason to be more concerned or less concerned about the threats of bioterrorism?

Dr. O'TOOLE. Well, Mr. Chairman, I think you're right. I think our response to naturally occurring epidemics should be seen as test runs. Everyone here has lived through a lot of natural epidemics at this point, and we have gotten better.

Again, I think for the first time we can actually contemplate the strategy of creating a foundation such that we could rapidly design and build, for example, a vaccine suitable for a particular threat in a much shorter time than is now the case. And I think we do have to prepare for a whole array of threats which we're not going to be able to predict.

The other issue that Dr. Shalala mentioned is that a lot of our response depends on the State and local public health departments. They have lost almost 50,000 people since 2008. And so one could argue that our capacity to respond to an epidemic today has diminished compared to then, and that's a problem.

Mr. MURPHY. Thank you.

Secretary Shalala and Congressman Greenwood, would it be fair to say that your bipartisan Panel's general concern is that biological threats are increasing while important aspects of U.S. bio-defense preparedness are actually declining or inadequate. Is that a proper conclusion? Ms. Shalala?

Ms. SHALALA. Yes, I think that's fair. And to echo Dr. O'Toole, our infrastructure for dealing with these has gotten weaker, starting with the State and local response. One of the things that we forgot in the Ebola discussion is the States are our first line of defense. We've been putting resources and building the public health infrastructure for years with essentially block grants from the CDC.

Those have been weakened. And if you don't have a State and local response—think about the outbreak of diseases caused by food poisoning, for example. It's that infrastructure that is the first line of defense for these biological issues that we're talking about. If we don't have a strong State role, with their laboratories, with their tracking systems, then it's very difficult for us to pick up something that's going to recur, that we know that's going to recur over a long period of time.

That's why we talk about the Vice President, because it's very difficult for anyone else to pull in all the actors, the private sector actors as well as the public sector agencies.

Mr. MURPHY. Well, given these things, Chairman Greenwood, so as we have increasing number of these naturally occurring and accidentally occurring bioattacks, is our diminished capacity just be-

cause we're strained or because we have actually lost ground in dealing with these issues overall?

Mr. GREENWOOD. Well, I think your original question—is the threat growing while the capacity to defend against it is decreasing?—the answer to that question is absolutely yes. So if you think about the bioterror threat and you think about ISIS and you look at what they've been able to do with rifles and assault weapons and so forth, it's clear and it's obvious that their intention is to kill as many infidels and apostates as they possible can. And you can do a heck of a lot better job at that using chemical and biological weapons than you can with convention armaments. They want to do that, and there is evidence that's been cited I think already that they are trying to figure out how to use bubonic plague. They are trying to have a plan to poison the Turkish water system. So the intention is clear.

While that's happening, the same technology, synthetic biology, gene editing, that is enabling our companies to do amazing things in terms of developing new drugs and new products, is also making it easier to formulate these new weapons.

And so the threat is growing. And to see that in the face of all of that the Federal Government's commitment to funding BARDA, to funding our abilities to develop these countermeasures is diminishing is frightening.

I'm glad you're having this hearing now, because the hearing you don't want to have is the one that happens after tens of thousands of people have lost their lives and you're sitting here asking yourselves and Government officials why we weren't ready.

Mr. MURPHY. Thank you. And that could happen at any time.

I see my time's up, and I'll recognize Ms. DeGette for 5 minutes.

Ms. DEGETTE. Thank you very much.

Mr. Greenwood, you're exactly right. This is what keeps me up at night, is the responsibility that this subcommittee has to actually move the ball forward, not just to have these hearings every so often. And the chairman will tell you, every year, like in about July, I start nagging to have a hearing on pandemic flu before we're actually in the middle of the flu season. But I think what the Blue Ribbon Panel is saying is we need to go even further than that. We need to have a system in place that's not based on response after the fact. Would that be your assessment too?

Mr. GREENWOOD. Absolutely. And if I may, let me describe to you what that system is.

The only thing that stands between these pandemic viruses and intentional bioterror attacks, the only thing that stands between those things and the safety of our people is, frankly, a handful of private companies in this country who were willing to take the risk of developing countermeasures. And as has been said, this is unique. You don't sell those countermeasures at Walmart.

Ms. DEGETTE. Right.

Mr. GREENWOOD. The only potential procurer of those is the Federal Government. And those companies, like every little biotech company, rely on investors. And those investors can put their money into a conventional biotech company, they can put it into an IT company, they can put it anywhere they want. They are looking for return on investment.

Ms. DEGETTE. Right.

Mr. GREENWOOD. And if they see a system that's uncertain due to lack of certainty that these products will be procured, they're going to put their money elsewhere.

Ms. DEGETTE. And we've really seen this in the pandemic influenza program and trying to prepare for that. And with these cuts, so I'm wondering, maybe, Secretary Shalala, you can talk about how the funding cuts have hampered a response to the potential pandemic flu outbreaks.

Ms. SHALALA. And I wouldn't underestimate, in addition to the private sector, those very fragile biotech companies, the importance of the National Institutes of Health and the fundamental science that we're doing, because if you don't have that, you wouldn't have the companies. So it's a combination of things.

Ms. DEGETTE. Yes. The problem is you need to get the basic research. And then you also need to have the robust pandemic flu program so that you can support development of the vaccine by the private company. So it really is a partnership.

Ms. SHALALA. Exactly. And vaccines have not been a major priority of the multinational pharmaceutical companies. They don't make enough money from them.

Ms. DEGETTE. Right.

Ms. SHALALA. They are marginal, particularly when the Government is the only purchaser.

Ms. DEGETTE. Right.

Ms. SHALALA. As was pointed out here, they don't have a lot of confidence that we're going to give them the kind of margins they can get from other kinds of investments. So this is a real challenge.

Let me make one other point. Health as a national defense issue is relatively new. Twenty years ago, no one was thinking about a national security issue related to some aspect of health. So think of this as the cutting edge of a dramatic new conceptualization of our defense. We're actually talking about the defense of a nation and about the health aspect of that.

Ms. DEGETTE. Right. Let me ask you, why is it that the Panel recommends centralized leadership in the Vice President's office to coordinate all of this?

Ms. SHALALA. Well, since I sat in the major agency responsible for many of these issues, and since we now have a Homeland Security agency, the fact is that the responsibilities for different aspects of this are spread across the Government. And even the lead agency concept will not solve that or, in my judgment, a czar sitting in the White House. The czars work best when there's an emergency.

But if you really want to build up the infrastructure, you have to have a powerful person. And you can't have that in a Cabinet agency which is a peer of all the other Cabinet agencies. So the Vice President is the only person that can cut through that, talk to the private sector, and simultaneously talk to State and local governments, and put all those pieces together. He's also the only person that can demand a unified budget out of the OMB and across the Government.

Ms. DEGETTE. And this was a bipartisan recommendation.

Ms. SHALALA. It was as bipartisan recommendation. And I have to tell you, I hesitated, as someone who sat in a Government agen-

cy, a powerful Government agency, I hesitate to transfer power to a Vice President or to the White House in general. As you know, Cabinet agencies have a certain amount of tension with White Houses. But at the end of the day, this is one of the areas where you need a unified budget. The only place we have a unified budget is actually in intelligence. So this is a parallel to that, to pull all the pieces together, and it's important enough to identify the Vice President. And Vice Presidents always have some time to take on other responsibilities.

Ms. DEGETTE. Thank you very much. Thanks.

Ms. SHALALA. With all due respect to our very nice Vice President.

Mr. MURPHY. I'm sure he'll be pleased that you said he has lots of time on his hands.

Ms. SHALALA. We have discussed this with the current Vice President. It's not he particularly that we identified, but the office itself.

Mr. MURPHY. We'll bring him in here and ask him about that. I recognize Mr. Flores for 5 minutes.

Mr. FLORES. Hard to follow that.

Dr. Parker, you emphasized in your testimony that we should be urgently preparing for biological threats in the time between outbreaks. And in 2006, as you know, Congress created BARDA to do exactly this. But as you explained, we continue to seem to go in crisis mode only when we have an outbreak. So what else should the Government do in these interepidemic periods?

Dr. PARKER. Well, thank you, Congressman Flores. And actually in answering your question, I'm going to come right back to the centralized leadership and how important that is. And I'll answer it actually with an example in my own experience and my own career.

In that very same time in 2006, as the Pandemic and All-Hazards Preparedness Act was passed, BARDA was created, we got very concerned about pandemic influenza to the point that an emergency supplemental was appropriated in that time, \$7 billion. It was accompanied by a very strong White House-led pandemic influenza strategy, coupled to a pandemic influenza implementation plan.

This is the closest example I think that has happened to date that kind of reflects the centralized leadership biodefense strategy that we actually did for pandemic influenza that accompanied an appropriation that really covered almost all the department agencies, State, local, private sector, that were involved in pandemic preparedness back at that time.

This implementation plan contained over 300 action items. It identified lead department agencies and supporting department agencies. It was very detailed. In fact, in my own department at the time, HHS, there was a lot of complaints that it was micromanaging and maybe superseding department authorities. Maybe it was. But we got stuff done. It allowed us to establish things that otherwise we would not have been able to do.

And so I just offer that as an example of something that we've already done. Let me also add that we were very responsible for meeting our milestones and metrics that were part of this imple-

mentation plan, both in the executive branch and to Congress, because all congressional committees that had the appropriate oversight for their department agencies were regularly being updated. Hearings were happening on progress of that plan.

So I just offer that up as an example of something in the past that I think is in the spirit of what the Panel has recommended that would drive us a long way forward to doing what we need to do in that interepidemic period and before an attack occurs.

Mr. FLORES. Well, thank you. I think that's helpful.

Also I want to compliment you on the great work that you're doing in the BARDA public-private partnership.

Dr. O'Toole, the World Health Organization recently assessed that the potential impact of synthetic biology on smallpox preparedness and control and the WHO scientific group found that the risk of reemergence of smallpox has increased due to the low cost and widespread availability of technology and know-how on how to create the smallpox virus.

So the BRSP focused heavily on the threats that we face today. Can you tell me what's possible given the rapid advances in synthetic biology, and how have these advances in synthetic biological escalated the threat?

Dr. O'TOOLE. Virtually anything is possible today theoretically. Smallpox is an ancient huge virus. It would be very difficult to create synthetically a functional smallpox virus. There are many other choices available. We know, for example, that the Soviets created a vaccine-resistant plague strain.

New gene-editing techniques make that kind of creation of resistant viruses quite straightforward, although nonresistant pathogens can do a great deal of damage too. I'm not sure it makes sense to go to the trouble of making a synthetic bug.

But what we are missing is the opportunities on the upside that synthetic biological and other advances allow.

Mr. FLORES. Right.

Dr. O'TOOLE. OK? I mean, we are in a revolutionary phase of biological science, and virtually none of this is being leveraged against our biodefense needs. We need a lot more than improved contracting procedures in BARDA. We need a commitment to revolutionize the way we make vaccines. Same thing with diagnostics.

We can do this. We can shift the advantage to biodefense. But we can't do this with incremental, you know, tweaks on the programs we have now, in my opinion. We need a much deeper investment in bioscience and biotech.

Mr. FLORES. OK. Thank you. That's helpful.

I've exhausted my time. I yield back.

Mr. MURPHY. Thank you.

I now recognize Mr. Tonko for 5 minutes.

Mr. TONKO. Thank you, Mr. Chairman.

Welcome to our witnesses.

Dr. O'Toole, in your testimony, you speak of the need to take advantage of recent developments in bioscience to rapidly develop tests and manufacture vaccines against emergent infectious diseases. Can you speak to the role that the centers for innovation in advanced development and technology play in this process? And is

this program indicative of the types of public-private partnerships we should be pursuing in this space?

Dr. O'TOOLE. I'm sorry, sir, I didn't hear. Centers for——

Mr. TONKO. Centers for innovation in advanced development and technology.

Dr. O'TOOLE. Yes, they can play a very critical role. For example, new diagnostics have a very difficult time getting approval to be paid for. So that discourages innovative biotech companies from making them. Imagine the difference it would make if we had a rapid diagnostic test right now for Zika and we could very clearly say, "You're infected, what is the outcome of your pregnancy?" or, "You're not infected." Same thing for Ebola. Imagine if we were able to tell within minutes if somebody was infected with Ebola, preferably before they're symptomatic.

The technologies for a whole host of new diagnostics are out there. The path to making money on them is very, very troubled, both from a regulatory point of view—it is almost as hard as it is to get a new drug through and the return on investment is not nearly as great—and also from the payment mechanism. So, yes, the centers have a tremendous role to play.

Mr. TONKO. Thank you.

And Secretary Shalala, how does the first recommendation that you've shared with us today get off the ground? Should there be a congressional mandate to have the executive branch explore and implement if experts agree it's needed? What are the next steps to take us forward?

Ms. SHALALA. You know, I'm not sure what the answer to that question is, whether Congress can designate the Vice President of the United States. It's a different branch. You certainly could make a recommendation in this area. And I think the fact that this committee would make a recommendation as part of a more integrated piece of authorizing legislation would have an effect.

It is a new recommendation. If you look through all of the other commission reports, this is the first time this has been elevated to this level. So I think both a combination of the visibility and some enthusiasm from Congress, from this committee in particular, would convince the next President of the United States to look at it very seriously.

And of course there are budget implications in that, particularly tying it to an integrated budget approach, which I think we all think is extremely important, and in which there have been very few examples at a very high level. Probably intelligence is the major one. The defense kinds of ones, you know, the defense agency itself usually leads. So it would take some identification by this committee, I think, that would make a difference.

Mr. GREENWOOD. Congressman, can I give 15 seconds on that?

Mr. TONKO. Sure, sure.

Mr. GREENWOOD. I'm not a lawyer, let alone a constitutional lawyer, but I think that the Congress can provide the authorization to the Vice President, and then perhaps it's up to the President and the Vice President to decide to utilize that authorization. But I think that's probably the way it would work.

Mr. TONKO. Thank you. Thank you to both of you.

And, Secretary Shalala, given the complications created by transferring technology from an innovator company to the centers for innovation and advanced development in technology, do you believe it would be beneficial to establish a single location wherein the complete process from innovation to manufacture can take place quickly and nimbly in order to rapidly respond to the various emerging threats?

Ms. SHALALA. You know, periodically the leaders of Government on both parties have looked at that process and seen whether we can fast track it so that we can get products faster to market. There are so many jurisdictional issues, if a product has to go through the FDA process, for example, if it's exempted from the FDA process.

So I think that that's an example where a Vice President looking at the process and making recommendations about the integration, because it's a piece of the larger strategy, where that would make a difference. We certainly did that when we looked at, during my time when we looked at fast tracking AIDS drugs, for example, and we were able to take different elements and put them together in a way that protected safety, but also moved the needle very quickly in that area. But that's why, because there are so many agencies of jurisdiction, you need someone to think it through.

Mr. TONKO. Thank you to each of you.

And Mr. Chair, I yield back.

Mr. MURPHY. Thank you.

I now recognize Mrs. Brooks for 5 minutes.

Mrs. BROOKS. Thank you, Mr. Chairman.

And thank you to our esteemed panel for being here today.

I was a U.S. attorney in 2001 and was part of the response in the anthrax attacks, and actually had an office where that powder was sent to. You know, multiple Government offices were receiving powder, which, you know, terrified that employee who opened the mail not knowing if it was actually anthrax or if it was just powder. And I have to tell you, I thought, and I was in Federal service until 2007 and it felt like we were moving forward, but I have to tell you, until this report came out, and until we have seen kind of the lack of adequate response to Ebola, quite frankly, I really do believe we have stepped back and that we have just moved from crisis to crisis.

But I just encourage my colleagues, this is an outstanding report with 33 recommendations. It is a roadmap. It is a blueprint. And it is in part the basis upon which Congresswoman Eshoo and I introduced 3299, the Strengthening Public Health Emergency Response Act of 2015. And I want to talk about that because I really appreciate all of these recommendations. I encourage my colleagues throughout Congress to read this book, because you as experts talked to experts around the country as well. It's not just the people on the Panel. A lot of work went into this. So I commend your work.

Mr. Greenwood, can you please share with us the merit that you see in returning the contracting authority to BARDA, back to BARDA, which is in my bill, and can you talk about the importance of that and what has happened and why we're not able to get, you

know, vaccines and our medical countermeasures through the pipeline as fast as we need them?

Mr. GREENWOOD. Well, thank you. Originally, the contracting authority was with BARDA and it was changed. It was moved to, I'm going to refer to my notes here, it was moved to the office, an office called the Acquisitions Management, Contracts and Grants Office. And the problem is that the technical experts are not there, and they are, in fact, at BARDA. And, in fact, because of certain regulations, there's a firewall between the two, and sometimes they actually cannot speak to one another.

Imagine how frustrating it is for a company trying to get a contract and it's talking to folks who know a lot about contracts but they don't know a lot about this issue, about medical countermeasures. And so I think it makes all of the sense in the world to eliminate that level of bureaucracy, put the contracting back at BARDA where it belongs so that the experts in the field can talk to the experts in the company with whom they are attempting to create contracts.

Mrs. BROOKS. Thank you.

And with respect to the companies trying to get vaccines into our stockpiles, can you and Dr. Shalala please talk about the fact that we don't have a sufficient coordinating mechanism in our National Strategic Stockpile also identified? So we don't even have, if I'm not mistaken, the right coordination between CDC and BARDA to have the right vaccines in our stockpile. Can you talk about that?

Ms. SHALALA. Yes. And we made recommendations in that regard, because the system is weak now and needs to be strengthened. And thank you, Congresswoman, for your leadership on this issue as well.

Mrs. BROOKS. Thank you.

Mr. Greenwood, any comments with respect to the stockpile?

Mr. GREENWOOD. Well, I think it goes to the essential point, which is that we are not organized as a Government to effectively and quickly respond to either pandemics or bioterror because the authorities are diffuse, they don't always talk to one another. And that is exactly why a central unified plan, a strategic plan, a central budget, and giving the authority to the Vice President makes all the sense.

Mrs. BROOKS. And I think citizens believe and know we have these stockpiles, and believe that they are adequately filled with the proper, right types of vaccines. Would anyone else like to comment on our National strategic stockpile?

Dr. O'Toole.

Dr. O'TOOLE. I'm the chair of the National Academy committee on the Strategic National Stockpile right now, and they have made tremendous progress in the last 20 years. The problem with the stockpile is that the new drugs that are going into it are largely biologicals, and they are very expensive, and they expire in 2 or 3 years. So there is a pipeline of new countermeasures coming in that increases inexorably the cost of the stockpile and everybody's budget is staying flat.

So the limitations on the countermeasures we have in the stockpile, first of all, are budgetary limitations. I mean, this is an expensive proposition. The stockpile already holds about \$7 billion worth

of stuff. But we are talking about having to cover multiple cities with these sometimes very expensive drugs and vaccines. We need a cheaper way to do it. Which is why I say you are never going to be able to create a stockpile that has everything you want in it against every contingency. We have to move to a strategy of being able to quickly design and manufacture at scale what we need.

Mrs. BROOKS. Thank you all for sounding the alarm. I appreciate your leadership.

I yield back.

Mr. MURPHY. Thank you.

I now recognize Mr. Mullin for 5 minutes.

Mr. MULLIN. Thank you, Chairman.

And thank you for the witnesses being here.

I first want to thank Ms. Shalala—I hope I say that right—and Mr. Greenwood for this report. I'll tell you, the more that I learn about it, the more I wish I wouldn't read it. I'm serious. It's very troubling when you understand the false security that we have even from something as simple, yet dangerous, as the flu to the most serious threats that we're facing today.

And in a previous hearing, I was talking about our CDC's National Stockpile, Strategic Stockpile that we have, and in particular the weaknesses that we have there. And following Mrs. Brooks here, I want to get a little bit more in depth about what you see as maybe our biggest weakness, maybe the biggest two weaknesses, some of the biggest threats we have with the stockpile, some recommendations. Don't get into it too deep. Just maybe one or two that we can start working on in the committee here.

Ms. SHALALA. Well, I actually think Dr. O'Toole is the expert on the stockpile issue and that she has outlined what the challenges are in the stockpile. It doesn't cover everything. It's expensive to maintain because they have a short shelf life. It was a good idea at the time, but constantly having to renew it is our biggest challenge.

I think that most of us think that there are other issues we can address, and certainly scientific issues that would give us a longer life in some of these areas. And I think on the production side, Tara, our ability to produce something faster and not being totally dependent on the stockpile is probably where your IOM commission is going.

Mr. MULLIN. You know, yesterday I had a meeting with some biodefense individuals and they were telling me that, you know, there is technology that they're looking at that would extend the shelf life through maybe a dry freeze. Is that correct? And then also, they are retesting it too, and some of it that was designed it'll go 2 or 3 years has lasted as long as 15 years. So they're constantly retesting it.

But how do we dispense it? How do we get it out? Having it in a stockpile is OK, but it doesn't do us any good if it's housed one place and we can't get it to where it's needed.

Ms. SHALALA. One of our recommendations was to use the existing community pharmacies. The original idea was to use the VA's because they are spread across the country and they do keep a certain amount of supplies.

Mr. MULLIN. We're having enough problems with the VA right now.

Ms. SHALALA. And they're well located, the VA hospital system and warehouse system. The Government has also contracted with, I think with FedEx, to move pallets around the country. And the reason for that is because the military is not well situated to do that kind of thing. So there has been extensive discussions in the Government and a strategy for moving pallets of drugs very quickly using—I think the contract was with the FedEx system originally to move pallets around the country when there are outbreaks.

Mr. MULLIN. Ms. O'Toole.

Dr. O'TOOLE. The big problem with the stockpile is traversing what's called the last mile. It's not about delivering the stockpile to the State public health departments. It's about getting it into the hands of people. And as you can imagine, that dispensing function is very complex.

Washington State is going through pharmacies. That won't work in every State, particularly rural States, although most Americans live within reach of a pharmacy. Advanced deployment is also being used in those very few States that can move very, very quickly to dispense, such as New York City.

One thing that would definitely help is more money for State health departments and local health departments to do drills on dispensing. These are invaluable, but they are very time consuming and expensive, and they simply don't have the money to do them. New York City does them, some of the big municipalities do them. But making those a more viable way to practice would, I think, make an appreciable difference.

Mr. MULLIN. That's a great recommendation.

Mr. Parker—Dr. Parker.

Dr. PARKER. Yes, I just wanted to come back. Everything you're asking actually really comes back to centralized leadership. We've been talking about lyophilization of vaccines for 15 years or more, the last model of dispensing medical countermeasures from our SNS. That is the hardest challenge.

In fact, there was an executive order in about 2009, 2010, and I was just discussing this with one of my colleagues from public health from Chicago yesterday. It seems that that work has just disappeared. But with centralized leadership, focused work on how to solve that last mile of actually dispensing the medical countermeasures would go on, and we need that. Because it's one thing to have a stockpile with Cipro and Tetracycline, and it's one thing to be able to get it FedExed to get it to an urban center. But actually getting it into people's hands is a huge unsolved problem.

Mr. MULLIN. Thank you. I'm out of time. I appreciate it.

Mr. MURPHY. Thank you. I now recognize Ms. Castor for 5 minutes.

Ms. CASTOR. Well, good morning, and thank you to the Panel for your terrific work on this important subject.

And Ms. Shalala, the folks at the University of Miami were so appreciative, and everyone across the country, for your service. I know they miss you there. But it's great to see that you continue on in your service.

I wanted to focus on hospital preparedness. During the Ebola outbreak in Africa in 2014, we took a critical look at hospital preparedness and its important role in our Nation's response biological events. At that time, in response to that, the President requested emergency supplemental funding for Ebola. The Congress responded. Now, with Zika, we're having to do that again. This doesn't seem to be the most efficient way to prepare for emergencies.

I'd like to ask a few questions about this, about what we can do to assist hospitals throughout the country in their response. You know, we had some that were very well prepared, like Emory University, what a terrific job they did because of their association with the CDC. And NIH, of course, was at the forefront in that Ebola response. But some did not do quite as well. And there's no mystery that if that had been more serious, that a lot of hospitals across the country would have struggled.

So what lessons do you think we learned from this, from the Ebola outbreak in Africa and the few cases that came to the U.S.? I'd like to ask maybe Ms. O'Toole first.

Dr. O'TOOLE. Hospital preparedness is very important. I think between 2002 and 2008 it did improve, for two reasons. First of all, disaster response drills are required for accreditation by JCAHO, by the hospital-accrediting facility. Again, for hospitals doing those kinds of drills, it's expensive and difficult.

There also was a CDC/HHS flow of money to hospitals to help them with bioterrorism and pandemic flu preparedness. And what happened with that money is the hospital started forming coalitions. In my city, in 2001, Baltimore, the mayor for the first time got all the CEOs of the hospitals together in one room. This is a private sector competitive industry. They don't necessarily cooperate, let alone collaborate.

And those CDC funds made a real difference. These regional coalitions of hospitals were used to figuring out how they were going to share resources, share information, et cetera, et cetera. That funding has been cut in half since 2010. That makes a big difference.

Ms. CASTOR. Secretary Shalala, the Panel's report mentions that disease-specific preparedness funding is the most inefficient and costly manner in which to fund preparedness. What are the alternatives to disease-specific programs, especially since many States have frayed their public health infrastructure? How can we respond better and give the hospitals in our local communities the tools they need?

Ms. SHALALA. We have specific recommendations in this area, including a steady stream of funding. We recommend that it be done through the accreditation system and through CMS.

In addition to that, we have recommended a tiered system. Every hospital in this country cannot be prepared for every complex disease. So both the regional coordination, but more importantly, identifying those hospitals that can have special rooms set aside.

In Florida, for example, all of us looked at—particularly at the great public hospital in Miami, whether we could build separate rooms with separate access to handle Ebola patients, and in fact went through an exercise to make that possible.

A great public hospital that sees all sorts of diseases probably is the best place to do that, as well as academic hospitals around the country. So creating a tiered system in which we know where we would send patients—once they are stabilized obviously—that would have the capacity and the separation to be able to handle these diseases is certainly the way to go.

We have some specific recommendations both on funding, on the accreditation process, but in particular on creating a tiered system in this country that would give us coverage across the country as there are outbreaks.

Ms. CASTOR. I think that is a very important recommendation and I would encourage the committee to act on it as soon as possible. Thank you very much.

Mr. MURPHY. Thank you.

I recognize Mr. Cramer for 5 minutes.

Mr. CRAMER. Thank you, Mr. Chairman.

And thanks to the panelists.

I want to focus on this incentive issue, Congressman, that you've raised.

And I will admit right up front that what I'm about to do is very dangerous. I want to think out loud for a little bit. And then I also admit that you're not going to adequately inform and educate me in 5 minutes. So you're going to have to come to my office and help me work through this idea, because you've all done a great job, as has the Panel, the Blue Ribbon Panel, in scaring me to death. So I'm adequately prepared to understand the threat, and I think that's very important.

But in our political world, of course, when it comes to the appropriations process, part of why I think you don't see Congress acting or the Government acting proactively is because we respond to the people we represent. And they will blame us when we're not prepared and they'll blame us when we spent money foolishly. And of course we're talking about finding a way to invest in something that we hope is never needed. And so that's our political dilemma.

I would, starting with you, Congresswoman Greenwood, and others if you want to weigh in, maybe just to elaborate a little on the SRF, the PRV, how we could help pharmaceuticals, the private sector, feel comfortable with the investment and the innovation. And we've talked a fair bit about it, but if there's a way we could elaborate just a little bit more to help me better understand how we're going to do this.

And I might also emphasize, is there a way to put a cost-benefit analysis on this? For example, Ms. Castor was talking about emergency responding. That's a cost. That's a cost that could be avoided, perhaps, if we were better prepared. Right?

So has there been some work done in that arena that helps me assure my constituents that we're not just appropriating, but that we're efficiently and effectively governing?

Mr. GREENWOOD. Well, thank you for admitting that we frightened you. And, obviously, our constituents, your constituents are not clamoring for this, because it is a sleeper.

No one is thinking that this is going to happen. And as I said earlier, the hearing you don't want to have is the one about why we were unprepared for the event that was so tragic.

So I think to some extent leadership involves informing your constituents, and this hearing is an important part of that, that this threat is real. I calculate when it comes to bioterror that they have the—the terrorists have the motive. They are trying to acquire the means. And despite our best efforts to deflect that, over time the likelihood of that happening is one over one, OK, it is going to happen.

Mr. CRAMER. Uh-huh.

Mr. GREENWOOD. And we have to be—you have to believe that, we have to believe that the threat is real.

So in terms of what works to be prepared, we talked about the contracting reform, which is a minor thing but an important thing, and Congresswoman Brooks is a leader on that. We've talked about the need for there to be sufficient funding to actually procure these MCMs when they're developed. The Secretary was completely correct when she said not to underestimate basic research at the NIH; that's critical.

But when it comes, just like in every other medicine that we develop, when it comes to actually developing the product and manufacturing the product, the private sector is the only place where that is done. And to invest money in that—the companies are willing to take the risk that maybe they will fail at the science, but the investors are not willing to take the risk that if they succeed the Federal Government is not going to be prepared to reward them by procuring the product.

So that's critical. And you need enough money over time to be certain, so there's a certainty that when you get to the end of the road and you get your product approved, that Congress hasn't moved the money around and it's no longer there.

Mr. CRAMER. Secretary Shalala, you may want to weigh in on this. But one of the things—I appreciate your national defense analogy, because I was thinking a lot about, you know, we spend billions of dollars on weapons we hope we never use, right? Now they do have the benefit of being a deterrent, understandably. But it isn't dissimilar. We have to constantly make this case. So I thank you for that. And the centralized leadership as well. I'm still struggling with the whole Vice President thing myself. But the more you talk about it, the more sense it makes. So I appreciate that.

Is there anything else anybody would add to what the Congressman said about the investment piece?

Dr. PARKER. Yes, I would like to add a little bit, and perhaps maybe just pull on the contracting itself as well. As we've heard, many of the companies in this space that are really contributing to biodefense, and particularly those that are bringing the more innovative solutions, are struggling themselves.

And the typical FAR-based Government contracting is really contrary to the biotechnology industry in and of itself.

And so I would think, you know, I have actually been encouraged recently with some pronouncements by DOD to begin to start using some authorities they already have, like other transaction authorities.

So I think just also taking a look at what are other things and just the basics of contracting that could make it more readily acces-

sible that the innovative biotechnology companies would actually do business with us in the Government is something to look at as well, sir.

Mr. CRAMER. Thank you very much. And if we could solve the DOD contracting in the context of this, that would be a bonus. That would be a cost-benefit analysis. Thank you.

Mr. MURPHY. Thank you.

I recognize now Mr. Green of Texas for 5 minutes.

Mr. GREEN. If we could solve the DOD contracting, we could probably have them audited.

I want to welcome our panel here.

The Blue Ribbon Study Panel on Biodefense highlighted vulnerabilities in our ability to combat emerging and reemerging infectious diseases, particularly drug-resistant infections, which could cause catastrophic loss of life and have already started to make even minor infections fatal. Without greater investment in antibiotics we face a future that resembles the days before these miracle drugs were developed, one in which people died of common infections, many medical advancements we take for granted become impossible, including surgery, chemotherapy, and organ transplantation.

The challenges presented by the rise of drug-resistant bacteria for which we have no effective treatments are representative of the challenge facing medical countermeasure product development. The market forces simply do not work and fail to foster the kind of pipeline we need.

In 2012, this committee passed and Congress passed the GAIN Act, and again in this current session, in the 21st Century Cures Act, we worked to remove the financial and regulatory barriers to antibiotic drug development.

Secretary Shalala, can you elaborate on the study's recommendation for incentivizing the development of medical countermeasures for emerging infectious diseases with pandemic potential? Specifically, please explain why there is such a need for Government to play a leadership role in this space.

Ms. SHALALA. Well, I think it's pretty straightforward that the only purchaser will be the Government. There's not a private sector market for these particular biologicals. And, therefore, the Government both has to incentivize the companies financially so that—and I think the other thing to understand—Jim, could explain this better than I can—these are relatively small companies, often with a small number of products. We've known a lot about the biotech industry. They're fragile. I like to use the word "fragile" when you talk about them. So that unless they know that they're going to be compensated and reimbursed for the cost of development, not just the cost of production, but the cost of development, unless there are financial incentives, I don't know how we're going to move very quickly in this area.

We've had some experience. Congressman Waxman in the Orphan Drug Act. We had a lot of diseases in which there were very small markets, at least initially, and the Congress in its wisdom passed legislation that encouraged companies to invest in creating drugs and treatments for a very small part of the population.

Our problem here is we start small, but we may need a production line that's huge at the end of the day. I don't know any other way to do it except with financial incentives. I just don't know. I think everything that we've learned, it's not just that I'm a capitalist, it's just that, from our point of view at a public policy issue, when the market is going to be the Government there is no other way to get a very small number of industry people to invest unless they know there's going to be a market at the end of the day.

Mr. GREEN. Jim. And, again, welcome back to your committee.

Mr. GREENWOOD. Thank you, Congressman. So nice to see you.

One of the proposals we have is the priority review voucher, the PRV. And the beauty of it, I mean, if you look at—Congress, in its wisdom, looked at neglected tropical diseases, and we knew that there's no financial pull, that these diseases that occur in places like Africa, the countries are so poor that they really can't afford to buy the product. So investors just aren't putting their money there.

When Congress created the priority review voucher, it works beautifully, because what it does is it says to a company, if I can get a drug approved, even if I don't make enough return on my investment from the procurement of that product, another, maybe a large biopharmaceutical company, will pay me. And these things have gone, there are only two or three of them have been sold, but they go—have gone for \$200 million, \$300 million, \$400 million.

It doesn't cost the taxpayers a penny. Pfizer or Merck or Glaxo or somebody buys that, which just simply gives them a foreshortened review period for some other product. And that doesn't cost the taxpayers any money either. They pay their PDUFA fee, they get their product approved. And sometimes they don't get their product approved. But if they do it, it gets approved a little faster. It gets on the market. And by the way, then it goes off patent sooner anyway. So it still doesn't have any cost to society.

Mr. GREEN. Mr. Chairman, I know I'm out of time, but we had legislation that's in the Senate that would fast track, because we recognize the Government is going to be the one that has to do it, because free enterprise can't invest that money for something. But there is legislation and hopefully the Senate will deal with Cures and the complete package that our full committee approved overwhelmingly.

Thank you, Mr. Chairman.

Mr. GREENWOOD. Thank you, Congressman.

Mr. MURPHY. That would be nice.

I recognize the vice chair of the full committee—I'm sorry, Doctor—well, Mrs. Blackburn.

Mrs. BLACKBURN. Yes, that woman from Tennessee.

I tell you what, Dr. Parker, I am so happy to see an Aggie on the panel. I've got Aggies in my family, and they always bring good, commonsense, seasoned wisdom to the table. So happy to see you there, and of course Mr. Greenwood, and how much we appreciate your insights on this and your dedication to the biotechnologies and the work that you've done there.

Just a couple of things that I want to touch base on. In talking with some of my research centers—and in Tennessee we have such

an aggressive biotechnology group. And when I was in the State senate, I helped to formulate that group. And so they've got a good underpinning. And it doesn't matter if it's Vanderbilt or St. Jude's or whatever. They talk to me a good bit about the right balance between Government and regulatory oversight and then the ability to incent.

And, Mr. Greenwood, I'm so pleased that you just mentioned the priority review voucher for the MCMs. I just think this is, when you look at these medical countermeasures, that is just so important that we have that. And it doesn't matter if it is a material threat, if it is something like Zika, we have to have a way to go about this.

But I want to come to something that Dr. O'Toole mentioned, and then, Congressman Greenwood, if you will kind of answer to that. Basically her point was you move products to a point of scalability, and then if you need something, you're ready to move with it and can push that scalability quickly.

So let's go back to that voucher, Mr. Greenwood, and if you'll continue that conversation and kind of build that, the importance of that, how you would address these for something that is a material threat. Or like the Zika virus, which right now there is not a vaccine and people are saying: What are you going to do, why didn't you know this was a problem, the Olympics are coming to Brazil, people have been vacationing for months in the zone that is affected, et cetera.

So let's go back to the importance of having that priority review process for this type of occurrence.

Mr. GREENWOOD. So there's great uncertainty for a company to—we've seen our companies, and proudly, jumping into the Zika issue and trying to do some research on it very quickly to develop products. But I remember a member company of Bio that was involved in trying to—it looked like it was close to having something on Ebola. And they almost didn't want to talk about it because their stock was fluctuating like this. All of a sudden everybody would invest in that company and then another company was doing something and people would pull out. And it created unpredictability and volatility. And so it's an example of how the norms of economics don't work in this field at all.

So the priority review voucher takes away one of the uncertainties. And that uncertainty is that it doesn't take away the uncertainty of: Can we make this product, and will it be safe, and will it be effective? That's always a risk. And I will tell you that doing that is harder than putting a man on the moon. Most companies fail and most projects fail. So it's hugely risky to even bother trying. But if you do try and you do succeed, the only reason your investors are giving you the leeway to go and do that is because they think that somehow they will get a return, a fair return on that investment.

One way to do that is to have enough money in the Reserve Fund and have it there not just year by year, but have it there multiple years so that companies can know and their investors can know, if we succeed here, they will buy the product and we will get our investment back.

But the priority review voucher is an entirely different way to do that, and because they have become so valuable, it is a huge driver, it is a huge incentive. Because if you can succeed—let's say that right now we had a priority review voucher for Zika, right, companies would know that if they could succeed, not only would they have the great satisfaction of being able to spare people from this disease and, God forbid, more children born with microencephaly, but that they would have this voucher they could then take to the marketplace and sell it at a very nice return and use that money to invest in the next countermeasure.

So I think it's a no-brainer to me. I know that there's some political questions about it, but I don't think there should be because it costs the taxpayers nothing, it costs society nothing, and it provides nothing but benefit.

Thank you.

Mrs. BLACKBURN. Thank you.

I yield back.

Mr. MURPHY. Thank you. The gentlelady yields back.

I now recognize Dr. Burgess of Texas for 5 minutes.

Mr. BURGESS. Thank you, Mr. Chairman.

Thanks to our panelists for being here today. I apologize for missing part of the hearing. We're having our budget season. Mr. Greenwood, you'll remember what that is like. So never a dull moment around here today.

Dr. O'Toole, I just want to ask you, because we've had several hearings over the past several years. Just for context, my congressional career goes from SARS now to Zika, long enough for people back home to say "term limits," but on the other hand, there may be some value in seeing some of this stuff over a continuum.

But you reference in your testimony about what are called laboratory developed tests. And Zika really comes in focus because, OK, you've got a polymerase chain reaction, but only a few places can do it. It's pretty valuable, pretty accurate, but it's hard to get. You got to go through a health department to get it. There is an IGM antibody, but it will cross-react with some other viruses, so you are not really sure if your result is accurate.

But would you just speak to the regulatory hurdles that you describe in your testimony and laboratory developed tests? Because we in this committee have been studying that. There is a movement, as you may be aware, to move the regulation of laboratory developed tests from CLIA, the Clinical Lab Improvement Amendment, which is basically administered through the Centers for Medicare and Medicaid Services, over into the Food and Drug Administration, and requires basically the licensing of laboratory developed tests just as if they were a new drug or device. And we know the problems with the timeline of those things. So could you just speak to that briefly?

Dr. O'TOOLE. Yes. Thank you for the question, Congressman.

First of all, the reason FDA is so concerned about diagnostics is that they can have life-or-death consequences. And we might want to think about different standards for diagnostics during public health emergencies.

Mr. BURGESS. Yes, I'm going to interrupt you for a minute. That is called clinical judgment, and you and I understand that because we trained as physicians, and that has to be part of the equation.

It took me 3 years to get from Dr. Shuren at the FDA a list of the problems that he was worried about with the development of laboratory developed tests. Where are the outliers? Where are the problems? To his credit, the last time he was in here, a few months ago, he did produce a list of 20 tests that he said that these may be problematic. But there are 11,000 laboratory developed tests out there, and they are useful every day of the week in a clinician's office. So I'm sorry, but continue.

Dr. O'TOOLE. So let me narrow the problem down to tests that we need for infectious disease, and particularly during epidemics, OK? And we need a variety of different kinds of tests. As you know, you want a very sensitive test when you have a low prevalence, but you don't want that same test when you're in the middle of an epidemic. So it gets tricky.

However, here's the problem. It's very difficult to validate a new diagnostic against Ebola, or even Zika, if you don't have curated samples of those diseases. In my view, the Government—you can put this in DOD, you can put it in HHS, you can put it in FDA—the Government should develop a curated bank of diseases about which we are worried so that companies, especially these small, agile, fragile companies, could come and test their diagnostics against them so that they could much more rapidly give FDA useful data on how well their test works. That's one.

Secondly, I think just as FDA has emergency use rules for medical countermeasures during public health emergencies, we ought to think about emergency use rules for diagnostics, which I think we can actually create rather rapidly and manufacture quickly during public health—

Mr. BURGESS. Yes, I will just tell you, last year or 18 months ago during the peak of the Ebola outbreak in September, I went to a hearing at the Foreign Affairs Committee where we heard that the FDA had actually put a clinical hold on, I think, a drug called TKM-Ebola that was at that time in use in treating patients with Ebola. I mean, I didn't want to hear about clinical holds, I wanted to hear about clinical trials. So it really did seem like they were an obstacle faced with this worldwide scourge.

Dr. Shalala, I just need to ask you a quick question on your—and I just appreciate your listing out the recommendations of the Blue Ribbon Task Force. In my political training, which, granted, was a street-level course, I was sort of taught that you only do three things. If you produce a list of 33 things, no one listens to you after the 3rd one.

But I did read through your list, and it is a good list, it's an exhaustive. I hope it's not static. Because one of the things that we've worked on, on the 21st Century Cures bill, is the whole issue of interoperability of electronic health records. And if we do not address that fact in this—in the recommendations that you have, I think that's actually going to stymie the ability for researchers and clinicians to communicate rapidly, de-identify data, to be sure, respect patient privacy rights. But at the same time, we need to have

that ability for rapid learning within the system, whatever developments.

Ms. SHALALA. Well, as you know, there has been a lot of progress on electronic medical records in this country and continues to be. And you're absolutely right, it's the touchstone piece.

I should say that even though we have 33 recommendations, we have actually staggered them, to identify those that we think Congress should do immediately that have more of a midterm value and a longer-term strategy. So we very carefully laid out a strategy that would be workable for Congress.

Mr. BURGESS. Thank you, Mr. Chairman.

Ms. SHALALA. And the Federal agencies at the same time. These are not just recommendations for Congress.

Mr. BURGESS. Very good. I yield back.

Mr. MURPHY. Thank you. The gentleman yields back.

I now recognize Mr. Bilirakis for 5 minutes.

Mr. BILIRAKIS. Thank you, Mr. Chairman. I appreciate this very much. Thank you for allowing me to sit in on this very important hearing.

As the former chairman of the Emergency Preparedness, Response, and Communications Subcommittee for Homeland Security, I recognize a need for the country to be proactive, not just reactive, to a host of biological threats, both natural and manmade. I'm glad that I can continue to be involved in the Energy and Commerce Committee. So I appreciate being given the opportunity to sit in on this subcommittee.

Secretary Shalala, earlier you mentioned that the State and local agencies are the first in line of defense against outbreaks and attacks. You also said that much of their funding through block grant programs has been weakened. What should we do to enable State and local entities to be prepared to respond to outbreaks or attacks? Is there enough of a focus on medical surge capacity and mass prophylaxis capabilities? Do we need flexibility in our grant programs?

Ms. SHALALA. Well, we have flexible grant programs. I think they are not well funded. That is our point, I think in the report, is that the funding has either been level or gone down over a number of years. The CDC's grant to the States is pretty flexible. I mean, there's some exceptions in it. But the States are really underfunded in terms of their infrastructure. As was pointed out, we have lost 50,000 public health experts across the country in the States because of—

Mr. MURPHY. Could you turn your microphone on, please?

Ms. SHALALA. Oh, I'm sorry.

We've lost 50,000 public health employees in our States and local governments as well, and that has to be properly funded. The tradition has been to have almost a block grant that goes from CDC to the States. I believe in that tradition. I believe in the relationship between the CDC and States and local governments to build an infrastructure. Because the CDC is not a line agency. When we're in an emergency we think they are. But it's really the States and the local governments and their public health departments that are responsible for both the tracking, the identification for all of us in this country. And we have to make sure that infrastruc-

ture—the States are under great fiscal pressure in this country and we have to make sure that infrastructure is beefed up, that stays in place.

Mr. BILIRAKIS. Thank you.

The next question is for the panel. You all mentioned the lack of comprehensive biodefense strategy and the need for centralized leadership. What, if any, protocol is in place now to enable coordination between the agencies, such as DHS, CDC, HHS, and various State agencies, when there is a disease outbreak? And what capability gaps exist in coordinating efforts between agencies? What makes coordination a challenge? We can start with the Secretary.

Ms. SHALALA. Well, I think earlier I talked about the fact that there were multiple agencies that are involved when we have an outbreak like this. And while HHS has very strong responsibilities and has the scientific and public health expertise, Homeland Security, the Defense Department, I mean, there are all sorts of agencies across the board.

And we have made a very strong recommendation that the Vice President be the ongoing coordinator in this country because the lead agency concept no longer works when you have various jurisdictions involved; and in particular, when you need to work with the private sector, with State and local governments. Unlike FEMA, which basically can order people around, it's very difficult for one agency. And I say this reluctantly because, as the former HHS Secretary, I wanted to own the world.

But when you don't have proper jurisdiction, when you don't have the leverage, then you have to elevate it, elevate both the responsibility. And we are much more sophisticated about the role of the private sector, the development of diagnostics, and that this has to all be part of our overall strategy in this country.

Dr. PARKER. Yes, I just want to add to that, and the need to be able to elevate it. And that centralized leadership not only is needed at the Federal level, and to try to close these gaps between each individual department and agency because they want to exercise their own authorities, but there are gaps between them.

But this will transcend all the way down to the State, local, private sector level. And it's only if you have centralized leadership coming from the White House, however that's done, it's going to help kind of break that and transcend that leadership.

And as an example you mentioned surge medical at the local level. It's not just a public health thing. In fact, it's going to be more logistics. That's why emergency management and other disciplines are going to be so necessary to effect, in your example, surge medical dispensing of antibiotics. It's more logistics. Public health doesn't do logistics.

So that's really why it's so important, this centralized leadership concept is just so critical, everything comes back to it, and it transcends the Federal, State, local, private sector levels, to close these gaps that we have between the multiple disciplines and agencies that have to contribute to biodefense.

Thank you.

Mr. BILIRAKIS. Thank you.

I'll yield back. Thank you, Mr. Chairman.

Mr. MURPHY. Thank you.

I now recognize Mr. Griffith of Virginia for 5 minutes.

Mr. GRIFFITH. Thank you very much.

Thank you all for being here today.

Dr. O'Toole, during the Ebola outbreak there were weaknesses identified in our system that we are now witnessing again with Zika: surveillance, detection, diagnostics. Overall, how would improved surveillance of animal disease outbreaks strengthen our surveillance of human disease outbreaks and make us better prepared for dealing with epidemics?

Dr. O'TOOLE. Well, the majority of emerging infectious diseases come from animals. They're diseases that affect both humans and animals. So we definitely need to do a better job looking at those hotspots where we are likely to see spillover from one species to humans.

Most of those hotspots are in tropical zones, in the jungles of South America and Asia and Africa. Most of our surveillance is in temperate zones, for starters. And we are now beginning to have tools such as high-sequencing genomics, high-speed genomics that could actually give us a much better handle of what diseases might be able to spill over. So we ought to think about funding field surveillance of these hotspot ecosystems, for starters.

Secondly, we ought to fund much more rigorously the USDA's existing program for looking at agricultural animals, because, you know, modern methods of agriculture put sometimes tens of thousands of animals together, creating our own industrial hotspots for spillover, and we have seen that with flu and the loss of turkeys and chickens in the past years.

Thirdly, for humans, we have to have a much more strategic approach to surveillance. We've spent billions, literally billions on surveillance in the past 15 years. Some things have worked; some things haven't. We've done a terrible job at lessons learned. And we ought to go back and figure out what really has made a difference.

Part of that is, again, we sound like broken records, funding State health departments, because that's where, you know, the rubber meets the road. But we have to help State health departments do a better job.

Diagnostics, again, critical, critical, critical, critical. Clinical disease is very vague. If you don't have the diagnostics to say this is Zika and this is dengue, you're going to have a hard time figuring out what's going on at the beginning and at the middle of an epidemic.

I would be very careful about investing large amounts of money in particular surveillance programs unless you know exactly what they're supposed to do, whether they work, and who's going to use that information.

Mr. GRIFFITH. Well, and my next question was going to be that, you know, are we doing an adequate job of integrating human, animal, and environment health. I think you already answered that by saying no, we're not doing such a good job of integrating those.

Secretary Shalala, how can we improve integrating those three components to develop a more comprehensive strategy to ensure that we are prepared for whatever's next?

Ms. SHALALA. I think our major recommendation is that we put this responsibility in the Office of the Vice President; that we really

need a national leader with the clout to integrate all these pieces and to help us—actually to help us think through a strategy, because the integration itself will have to be done by agencies and by others. But the strategy, having the metrics for it, keeping people accountable, we've all recommended that we elevate that to the Office of the Vice President.

Mr. GRIFFITH. I appreciate that.

Dr. O'Toole, lots of concerns being raised about Zika and our athletes competing this summer in the Olympics; not only our athletes, but all the spectators who will go down, the coaches, the family member, et cetera. Do you believe that we will be ready? Obviously, the Brazilians are going to have to do some things and this is an international effort. But do you believe that we are going to be ready to be able to defend our folks or have the biodefense efforts ready to defend our athletes and spectators and coaches and family members who go to the Olympics this year?

Dr. O'TOOLE. Well, I understand the deep concern that Zika has raised. Whenever children are affected, you know, grownups get deeply, deeply worried, and that's what's happening here.

I will say that there are dozens of very dangerous mosquito, and even tick-borne diseases, that have been with us for millennia. And you can to some extent protect yourself from mosquito bites by using DEET and dressing well and sleeping in places with screens and so forth. That's not a perfect protection. It's not a zero risk.

We have to wait and see until we have more information about what is really going on. We've known there has been more or less an epidemic of dengue and Chikungunya. And dengue is a serious disease in South America for a few years. That hasn't stopped people from going down there.

I think we have to wait till there is more scientific data about Zika. I know NIH is working on a vaccine. I wish we had one. But I think if I were a young woman who was pregnant or getting pregnant, I'd think twice about going to South America right now. But I think for most people there are ways to at least mitigate the risk.

Mr. GRIFFITH. All right. Thank you.

I yield back.

Mr. GREENWOOD. Mr. Chairman, would you indulge me 30 seconds on the Zika question?

Mr. MURPHY. Yes.

Mr. GREENWOOD. Thank you.

I just wanted to point out that, aside from medical countermeasures on Zika, there's a whole field of looking at how to bio-engineer mosquitos, which we already know how to do, so that they are actually—they're all males, they don't bite, and they mate with the females, and the progeny don't survive. And I think that's a fascinating new technology that may be part of the solution to this problem.

Mr. MURPHY. Thank you. Thank you. I know we have votes in a few minutes.

But Mrs. Brooks, if you have one quick follow-up question.

Mrs. BROOKS. One quick follow-up question—thank you, Mr. Chairman—to Mr. Greenwood, with respect to the priority review voucher program.

Can you share with us existing PRV programs for rare pediatric disease or neglected tropical diseases increasing the biotech investments in this area? Can you give us some examples where you've seen that already happen?

Mr. GREENWOOD. I probably have that in my notes, and if I had time, I'd be whispered to behind. But I'd just say—

Mrs. BROOKS. And if you would like to submit it for the record, that would be fine.

Mr. GREENWOOD. We'll submit that for the record.

[The information appears at the conclusion of the hearing.]

Mr. GREENWOOD. But suffice it to say that it is working. It has created, both in the area of pediatrics and in the area of neglected tropical diseases, it has generated a tremendous amount of interest and investment. And it is working perfectly well, just as a Congress intended, and I have no doubts that it would well in this field as well.

Mrs. BROOKS. And do you believe that if we added the DHS' material threats to the FDA's PRV program, it would spur additional development of the medical countermeasures?

Mr. GREENWOOD. I think that is precisely what needs to be done, and I have no doubt whatsoever that it will be successful in inspiring investment in this very dangerous field.

Mrs. BROOKS. Thank you all.

I yield back.

Mr. MURPHY. Dr. Burgess, do you need a quick follow-up question?

Mr. BURGESS. Yes.

And, Secretary Shalala, you've spoken about the Vice President as sort of the overseer of all of this, and I appreciate the fact that there are too many agencies and too many people involved, and when too many people are in charge, no one's in charge, and I get that.

Ms. SHALALA. And too many committees of jurisdiction.

Mr. BURGESS. And I don't quite share your enthusiasm for putting this into the executive branch. Perhaps it should be a Speaker's position. But, nevertheless, I will just tell you, I was down at the border, that Low Rio Grande border last weekend, and you realize you've got a CDC map that shows Mexico and Central America being purple with Zika, and my State's the other side of a relatively narrow river. It just seems to me we don't pay enough attention to border control. I know you can't stop mosquitos at the border, but really the issue is stopping people who are infected or potentially infected.

And right now we are undergoing another surge of unaccompanied minors and family units. And to the best of my ability to detect, we're not looking, and that is a point of great concern to me. So all of the other things we've talked about are extremely important, but let us not forget border control, because that's an issue as well.

Ms. SHALALA. Well, I'll leave that to your comments. But I would say that we also have to beef up global health, and that is PAHO, the Pan American Health Organization, which is part of the World Health Organization.

We can't stop mosquitos from coming across borders, whether it's in people or they're just flying across. But it's not only beefing up our own infrastructure. One of the things that we learned with Ebola is that the World Health Organization doesn't have the kind of authorities it needs. It doesn't have the resources they need.

And so it's not just a State and local issue or a Federal issue, it's also an international issue. And I think your point about border security is also. But I would put it in the context of international health security and looking at the agencies that we have now, the international agencies that we have now.

And we know that they're weak. We learned that during Ebola and previously. And this committee also might have a hearing, because there have been recent reports on the international health organizations, to take a look at those relationships as well.

Mr. MURPHY. Thank you.

I know they're going to call votes at any moment here. I just want to follow up with two quick questions. If you can't answer this here, get back to us. I'd like an answer from each of you. If you know of countries that have model programs to do the very thing you're describing, we'd love to know about that. Does anybody know any offhand, or would you like to get back to us on that?

Mr. GREENWOOD. My only comment, Mr. Chairman, is that if we don't have it, I'd be very surprised if anyone else in the world—

Mr. MURPHY. That's what I feared.

Ms. SHALALA. To be fair, there are centralized health systems in smaller places that may be more integrated, but I think that we have different levels of Government, different levels of responsibility. We can't use their models. We'll have to put our own system together.

Mr. MURPHY. Thank you.

Another question, just hope you can get information to us for the record. Given the recent GAO report on the failings of BioWatch programs, including the lack of valid performance data, should we continue to fund it? Do you have an answer for that, or do you want to get back to us?

Mr. GREENWOOD. I'm sorry. Would you repeat the question, Mr. Chairman?

Mr. MURPHY. Should the Federal Government continue to fund the BioWatch program given the recent GAO report on its failings and problems, including the lack of valid performance data?

Mr. GREENWOOD. I think we probably will get back to you on the record with that.

[The information appears at the conclusion of the hearing.]

Mr. MURPHY. Ms. O'Toole, can you answer that?

Dr. O'TOOLE. I'm a longtime critic of BioWatch, but I think you should continue to fund the current program for a defined period of time until we have a strategy for what we're going to go do next. I think the notion that BioWatch, or even the next-gen BioWatch, a series of environmental sensors, can protect the country is wrong-headed. The technology just isn't good enough. Its cost-effectiveness ratio is just not advantageous.

We need a new generation of technology. It's not there yet. Again, diagnostics would make a big difference. You do need these

sorts of sensors to protect high-risk targets and national security events and so forth.

The problem with BioWatch right now is it is not characterized, as GAO points out very graphically and I think accurately. We don't know that it works. It's not clear that it doesn't work. It has a very limited range of bugs that it looks for. And to really cover an area of a city you would need a lot of those machines. So it would be very expensive.

Mr. MURPHY. Thank you.

Well, with that I want the committee—first of all, thank you—

Ms. DEGETTE. Can I just say one thing?

Mr. MURPHY. Oh, yes. Ms. DeGette.

Ms. DEGETTE. Thank you.

First of all, with all due respect to my friend from Texas, I don't think that any kind of border control, even building a wall, is going to stop these vector-borne diseases from coming over. And I know that's not what you mean.

But what it does really highlight is how we are an international community. It's not just the mosquitos coming. We even had Ebola cases come here because of international travel. And so that's why it's so unbelievably critical that we take this report seriously and that we really work hard as a committee.

And, Mr. Chairman, I just want to commend you again for calling this hearing. I know you're planning to have a classified briefing when we come back from the February recess, and I think that's a good other step.

And then I would just finally offer my input and the input of the minority staff and members to help come up with a robust hearing schedule for the rest of the year. I think if there's nothing else we do than spend our time on this report and the recommendations, trying to get our arms around it and get that sense of urgency to our respective leaderships, then it will have been successful.

And I want to thank everybody again from the commission for doing this deep dive because it really is important.

Mr. MURPHY. And let me also announce on March 2 we will have a hearing on the Zika virus where many of these issues will come up, we'll take a deep dive in that, as well as what my friend said about getting into a classified briefing on some of biodefense issues, critically important, and should be a wakeup call for America. But as you've said a couple times, Mr. Greenwood, we may not do these things until after the fact, and that would be a tragedy. So we'll get moving on that.

So in conclusion, again, I want to thank all the witnesses and members for participating in today's hearing. I remind members they have 10 business days to submit questions for the record. I ask all the witnesses to agree to respond promptly to the questions.

And with that, this committee hearing is adjourned.

[Whereupon, at 11:05 a.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]



U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE

February 10, 2016

TO: Members, Subcommittee on Oversight and Investigations

FROM: Committee Majority Staff

RE: Hearing entitled "Outbreaks, Attacks, and Accidents: Combatting Biological Threats"

The Subcommittee on Oversight and Investigations will hold a hearing on Friday, February 12, 2015, at 9:00 a.m. in 2123 Rayburn House Office Building, entitled "Outbreaks, Attacks, and Accidents: Combatting Biological Threats." The Subcommittee will hear testimony from members of the Blue Ribbon Study Panel on Biodefense and other experts on (a) the current threat of natural, intentional, and accidental biological events against the United States, (b) the extent of our preparedness for such an event, (c) the need to modernize our approach to biodefense preparedness, including addressing the lack of leadership on the issue within the Federal government, and (d) other specific recommendations by the Blue Ribbon Panel that fall within the jurisdiction of the Energy and Commerce Committee.

I. WITNESSES

- Donna Shalala, Panel Member, Blue Ribbon Study Panel on Biodefense;
- James Greenwood, Panel Member, Blue Ribbon Study Panel on Biodefense;
- Tara O'Toole, M.D., M.P.H., Senior Fellow and Executive Vice President, In-Q-Tel;
- Gerald Parker, D.V.M., Ph.D., M.S., Associate Vice President, Public Health Preparedness and Response, Center for Innovation in Advanced Development and Manufacturing, Texas A&M University.

II. BACKGROUND

a. The Blue Ribbon Study Panel on Biodefense Report

The Blue Ribbon Study Panel on Biodefense (Panel) was established in 2014 to assess gaps and provide recommendations to improve U.S. biodefense. The Panel, chaired by Senator Joe Lieberman and Secretary Tom Ridge, charged itself with this work and did not receive a commission from Congress or the President. The Panel held a series of public hearings, hearing from experts at all levels of government, industry, academia, and advocacy, before issuing its report in October 2015.

The Panel's report makes clear that this threat is not new. In fact, many of their recommendations are based on previous recommendations made by earlier panels or commissions. For example:

- The U.S. Commission on National Security/21st Century, also known as the Hart-Rudman Commission, "recognized the potential for epidemics to become pandemics and the dual-use nature of scientific discoveries."¹
- The Commission on Terrorist Attacks on the United States, also known as the 9/11 Commission, "posited that more than two dozen terrorist groups were pursuing biological materials but that high-level government leaders were expressing various levels of concern regarding this threat."²
- The Commission on the Intelligence Capabilities of the United States Regarding Weapons of Mass Destruction echoed the concerns of the earlier commissions and "described in excruciating detail the failings and weaknesses of the [Intelligence Community] regarding the biological threat."³
- The Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism "determined that the priority placed on addressing the biological threat was too low to ensure national security."⁴

Many of the Panel's recommendations—33 in all—address the need for a comprehensive plan for biodefense with a clear leader. Better leadership is needed to achieve coordination and accountability, improve collaboration, and drive innovation across the numerous biodefense programs in the Federal government in particular.

Unlike previous commissions, the Blue Ribbon Panel does not plan to disband now that their report has been released. This year, the Panel will begin assessing the government's implementation of its recommendations. The Panel also plans to begin an agency-by-agency review the United States' biodefense preparedness, which will be more specific than the overview assessment discussed in the Panel's report.

i. The Threat of Natural and Intentional Biological Events

The Panel believes that the biological threat to the United States—including natural and intentional incidents—is growing. Our understanding of, and response to, the threat must be elevated accordingly.

¹ Bipartisan Report of the Blue Ribbon Study Panel on Biodefense, *A National Blueprint for Biodefense: Leadership and Major Reform Needed to Optimize Efforts* 5 (Oct. 2015) [hereinafter Panel Report].

² *Id.*

³ *Id.*

⁴ *Id.*

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Pandemic and other highly pathogenic or emerging diseases are occurring with greater frequency and spreading more quickly throughout the world. The same mosquito, for example, spreads the Zika, Dengue fever, and Chikungunya viruses. These diseases do not just affect the human population. Naturally occurring diseases also have an impact on livestock, crops, and dairy or produce supplies.

Since 2002, the world has seen outbreaks of severe acute respiratory syndrome (SARS), Chikungunya, Zika, cholera, influenza, measles, Ebola, and Middle East respiratory syndrome (MERS). Most of these outbreaks have occurred since 2008.⁵ Appendix 1, a timeline of outbreaks since 2002, demonstrates the increasing frequency of infectious disease outbreaks, epidemics, and pandemics. As noted by the Commission on a Global Health Risk Framework, the rate of emergence of new infectious diseases appears to be increasing.⁶ This seems to be the result of the following factors: greater probability of zoonotic (animal to human) transmission because of increased population and consequently greater human-wildlife interaction and increased livestock production, and ever-increasing global trade and travel.⁷

With respect to the intentional (e.g., terrorist) threat, it is easier for nation states and terrorists to obtain the resources necessary to produce biological weapons than ever before. Further, given in part the ease with which one can obtain these resources, it is difficult for the intelligence community to collect, analyze, and produce intelligence about biological threats. Former Representative Mike Rogers who chaired the House Permanent Select Committee on Intelligence told the Panel, “the longer [terrorist groups] have freedom of operation in any space that contains those kinds of elements, I think that’s dangerous to the United States and our European allies.”⁸ Many groups, including terrorist organizations, domestic militia groups, and lone wolves, have expressed the intent to use and have shown some capability to develop biological weapons. While events of this nature have previously been described as “low probability-high consequence,” the better classification of likelihood and consequence today is “indeterminate.”⁹

A recent report published by Gryphon Scientific for an NIH advisory committee details terrorist and extremist events tied to biological warfare since 1972. With respect to the capabilities of transnational terrorist groups in particular, Gryphon Scientific found that the groups are “well-funded, well-organized, well-armed, and highly motivated . . . They are capable of orchestrating complex attacks and have suitable resources to orchestrate long-term plots . . . They may have a chemical or biological weapons program involving scientifically trained individuals . . .”¹⁰ Appendix 2, a timeline of bioterror events since 1972 and currently designated foreign terrorist organizations, shows the historical progression of bioterror attacks and the large number of groups who may attempt to procure biological weapons. This historical information, coupled with the “indeterminate” risk assessment, demonstrates that the likelihood of such an attack is not as remote as one would hope.

⁵ Sands, et al., *The Neglected Dimension of Global Security--A Framework for Countering Infectious Disease Crises*, NEW ENGLAND J. OF MEDICINE (Jan. 13, 2016)

⁶ *Id.* at 4.

⁷ *Id.*

⁸ Panel Report, *supra* note 1., at 4

⁹ Briefing by Dr. Tara O’Toole to Committee staff (Feb. 3, 2016).

¹⁰ Gryphon Scientific, *Risk and Benefit Analysis of Gain of Function Research* 850 (Dec. 2015).

With respect to ISIS in particular, recent press reports indicate that ISIS militants are seeking biological weapons. According to non-classified sources, in August 2015, a Syrian rebel group reported that they found a laptop belonging to ISIS that included documents on biological weaponry.¹¹ On October 7, 2015, Brigadier General Maria Gervais, head of the Army's Chemical, Biological, Radiological and Nuclear School stated, "Intelligence has recently discovered that ISIS intends to pursue biological agents and is also trying to figure out how to weaponized bubonic plague through the use of infected animals."¹² In November 2015, ISIS executed the head of the Department of Physics at the Department of the University of Mosul, reportedly because of his refusal to develop biological weapons.¹³

Nearly all of the pathogens at issue in either a bioterrorism event or a pandemic are zoonotic, which means that they reach humans through animals. Emerging infectious diseases, for example, are often first seen in areas where human populations are putting pressure on remote wildlife habitats, such as near a rainforest.¹⁴ Accordingly, the Panel promotes a "One Health" approach, utilizing disease surveillance and detection in both human and animal populations.

ii. The Need for Leadership and Collaboration on Biodefense Issues

The Panel believes that the lack of leadership and the fractured nature of responsibilities on biodefense issues is a major factor in our lack of preparedness for an intentional or natural biological event.

Currently, biological responsibilities are spread across numerous departments, agencies, and programs. There is no central leadership in the U.S. government accountable for strategic planning, budgeting, or coordination. The Department of Defense handles biological programs related to national security. The Department of Health and Human Services (HHS) has responsibility for biological threats to humans, while the Department of Agriculture (USDA) has similar responsibilities for animals and plants.

Each of the last three Presidents has addressed biodefense staffing differently. During President Clinton's administration, former Secretary of Health and Human Services Donna Shalala detailed an assistant surgeon general from the U.S. Public Health Service to the National Security Council.¹⁵ During the Bush administration, Assistant to the President Tom Ridge created a biodefense directorate in the Homeland Security Council staffed with a Special

¹¹ Harold Doornbos & Jenan Moussa, *Found: The Islamic State's Terror Laptop of Doom*, FOREIGN POL'Y (Aug. 28, 2014) (available at <http://foreignpolicy.com/2014/08/28/found-the-islamic-states-terror-laptop-of-doom/>) (last accessed Feb. 5, 2016).

¹² Sarah Sicard, *ISIL Determined to Acquire Biological Weapons*, NAT'L DEF. MAG. (Oct. 7, 2014) (available at <http://www.nationaldefensemagazine.org/blog/lists/posts/post.aspx?ID=1632>) (last accessed Feb. 5, 2016).

¹³ Abdelhak Mamoun, *Source: ISIS executes Head of Physics Department for refusing to develop bioweapons in Mosul*, IRAQI NEWS (Nov. 12, 2015) (available at <http://www.iraqinews.com/iraq-war/source-isis-executes-head-physics-department-refusing-develop-bioweapons-mosul/>) (last accessed Feb. 5, 2016).

¹⁴ Briefing by Dr. Tara O'Toole to Committee staff (Feb. 3, 2016).

¹⁵ Panel Report, *supra* note 1, at 7.

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Assistant to the President and three additional staffers.¹⁶ President Obama merged the staffs of the National Security Council and the Homeland Security Council, eliminating the biodefense office. Currently, the various biosecurity functions are distributed through the National Security Council. In 2014, President Obama also appointed an Ebola czar, who has since retired, to coordinate the Federal government's response to that crisis from the White House.¹⁷

The Panel believes the current biological preparedness and response construct is too fragmented to ensure an effective national strategy. Accordingly, it recommends that biodefense be institutionalized in the Office of the Vice President. In the opinion of the Panel, the Vice President should receive the necessary jurisdiction and authority to coordinate the various biological groups throughout the federal government, and also receive authority to review and advise on all biodefense budgetary issues.¹⁸ The Panel further recommends that the Vice President establish a biodefense coordination council within the White House and develop, implement, and update a comprehensive national strategy for biodefense.¹⁹

iii. Preparing for a Biological Event

The Panel identified numerous specific areas where the Federal government must improve its efforts to implement an end-to-end biodefense system. According to the Panel, the United States "remains unprepared for known, unknown, and unexpected threats."²⁰

The 2014 Ebola outbreak demonstrated the current state of preparedness for an outbreak. Most hospitals were unprepared to handle the disease. In a departure from normal procedures in which the Occupational Safety and Health Administration (OSHA) developed guidelines for hospitals, the Centers for Disease Control and Prevention (CDC) instead developed flawed guidelines. The Panel described the overall preparedness at the hospital level:

Flawed guidelines released by the CDC to hospitals (which addressed issues not under CDC purview, such as [personal protective equipment] and hospital operations), inadequate coordination between CDC and OSHA regarding federal messaging and waste management, poor training regarding the implementation of the requirements described in those guidelines, and insufficient attention paid to some potentially useful hospital disaster plans exacerbated already insufficient levels of preparedness.²¹

In the wake of the Ebola outbreak, HHS provided grants to help hospitals better address Ebola in the future. Yet, as the Panel points out, disease-specific funding is inefficient and is not the best way to fund preparedness for future attacks—which may or may not involve the same pathogen.

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ *Id.* at 9.

¹⁹ *Id.* at 11-15.

²⁰ *Id.* at 52.

²¹ *Id.* At 38.

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Efficiently and effectively preparing for biological events will require innovation in several key areas. Accurate biosurveillance and biodefense capabilities are among the most critical elements of an end-to-end approach. The systems must work quickly—detecting the presence of a pathogen in hours, not days. The Panel recommends that the Federal government implement an integrated national biosurveillance capability that works, unlike the numerous surveillance and detection systems—including the ineffective BioWatch program—currently in use. Further, this network should share data among the various agencies, including that collected by the CDC, USDA, and other entities, and also improve surveillance of animal pathogen data.

BioWatch, a Department of Homeland Security (DHS) biosurveillance program launched in 2003, is criticized by the Panel for failing to realize its potential over the last 12 years. BioWatch detectors, deployed in a few dozen cities, collect air samples for a select number of bioterror pathogens. The samples are analyzed by non-Federal public health laboratories. The Panel described the limitations of the system: “it relies on winds blowing in optimal directions”; “it can take up to 36 hours to alert the possible presence of a pathogen”; “specimens are inactivated, preventing determinations of whether live organisms were released”; “it cannot differentiate between normal background bacteria and harmful pathogens”; and “it cannot identify atypical threats.”²² DHS failed to acquire next-generation technology that could have reduced time-to-detection to as few as 6 hours, so the program uses the same technology as it did upon deployment in 2003. The Panel recommends that a new, advanced environmental detection system be developed to replace BioWatch. As discussed below, the U.S. Governmental Accountability Office (GAO) also recommends that the government in effect end BioWatch.

The development of flexible medical countermeasures will allow for a timely response to a number of different scenarios. While traditional vaccines can address specific threats, platforms that allow for rapid vaccine development and production may have the flexibility to address as-yet-unknown threats. The development of rapid diagnostic tests would aid physicians in identifying emerging diseases or select agent pathogens. For example, the availability of such a rapid diagnostic test would have significantly improved patient screening during the Ebola crisis. In order to develop new medical countermeasures and rapid diagnostic tests, the Panel believes that government research agencies, such as Biomedical Advanced Research and Development Authority and the National Institutes of Health, should prioritize innovation over incrementalism in research and development.

b. Additional Panel Recommendations Within the Committee’s Jurisdiction

The Blue Ribbon Panel report includes 33 recommendations across the entire government. Many recommendations fall within this Committee’s jurisdiction, including:

- **Prioritize emerging and reemerging infectious diseases.** The Panel recommends that the Secretary of Health and Human Services, along with the Secretaries of Agriculture and Defense, develop a multi-criteria tool to prioritize emerging infectious disease threats.²³

²² *Id.* at 59.

²³ *Id.* at 21.

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- **Prioritize and align investments in medical countermeasures (MCM) among all Federal stakeholders.** Federal agencies must prioritize and budget for the right countermeasures, focusing in greater part on specific product goals and end-user needs, such as medical countermeasures for specific diseases or pathogens (i.e., Ebola).²⁴
- **Establish and utilize a standard process to develop and issue clinical infection control guidance for biological events.** Federal agencies must standardize the development of clinical guidelines before an event occurs, and not change those processes in the midst of an event.²⁵
- **Develop and implement a medical countermeasure response framework.** An operational plan to distribute and dispense MCMs could speed the allocation of vaccines or other countermeasures from the Strategic National Stockpile or local supplies.²⁶
- **Allow for forward deployment of Strategic National Stockpile assets.** Providing assets to qualified cities in advance is a near-term solution while a broader medical countermeasure response framework is developed.²⁷
- **Harden pathogen and advanced biotechnology information from cyber attacks.** Databases containing genetic sequences of pathogens, advanced methods for genetic engineering, or other biological information may be stored on cloud systems vulnerable to cyber attack.²⁸
- **Review and overhaul the Select Agent Program.** The regulatory regime of the program does not fully address underlying issues, including pathogen safety and security.²⁹
- **Address prioritization and funding for influenza preparedness.** The Panel recommends that Congress consider providing complementary legislative authorization to define and guide pandemic influenza programs.³⁰

c. Other Recent Reports on Biopreparedness

Since the Blue Ribbon Panel's Report was published, several reports published by the GAO and one by the DHS Office of Inspector General (OIG) have been released. Given that these reports were released after publication of the Blue Ribbon Report on Biodefense, the Panel was not able to consider the findings of these reports and incorporate them into their work. These reports highlight the importance of the work done by the Panel and the

²⁴ *Id.* at 22.

²⁵ *Id.* at 38.

²⁶ *Id.* at 43.

²⁷ *Id.* at 44.

²⁸ *Id.* at 46.

²⁹ *Id.* at 60.

³⁰ *Id.* at 56.

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recommendations that they made. The findings and recommendations of each report are summarized below.

i. BioWatch

On October 23, 2015, GAO released a report entitled, “Biosurveillance: DHS Should Not Pursue BioWatch Upgrades or Enhancements Until System Capabilities are Established.” The GAO found that DHS does not have reliable information about BioWatch Generation 2’s (Gen-2) ability to detect a biological attack and as a result is not able to make informed decisions about whether or not we should upgrade the system. DHS still lacks performance requirements that would allow for accurate interpretation of test results and the ability to make conclusions about BioWatch’s effectiveness and reliability. It was also discovered that DHS tested Gen-2 by using simulated biothreat agents in a chamber, rather than in real world settings, which limited the validity of the results. Despite all of this uncertainty, DHS took steps to acquire and test a new generation for BioWatch, Gen-3. DHS canceled Gen-3 acquisition in April 2014. However, GAO reports there are components of Gen-3 that could be applied to upgrade Gen-2 rather than acquiring a next generation. As a result of their findings, GAO recommended that DHS wait to pursue upgrades to Gen-2 until it can establish the system’s current capabilities with certainty, and DHS generally concurred with GAO’s recommendation.³¹

ii. Emerging Animal Diseases

On December 15, 2015, GAO released a report entitled, “Emerging Animal Diseases: Actions Needed to Better Position USDA to Address Future Risks.” The GAO found that the USDA failed to take regulatory action during the initial response to the outbreaks of Swine Enteric Coronavirus Diseases that started in May 2013, because the agency did not believe that such action was necessary. USDA supported industry-led efforts, but due to a lack of data collection, USDA does not have information regarding the location of where the outbreak originated. USDA also acknowledged that they failed to follow their guidance that requires them to perform epidemiological investigations at the onset of an outbreak. Due to USDA’s inaction, it is unlikely that we will ever know the source of the disease. In June 2014, USDA issued an order with reporting requirements of newly infected herds. They have also drafted guidance, but the guidance does not include important details involved in a response, such as roles and responsibilities. As a result of their findings, GAO recommended that USDA develop a process to help guarantee its guidance for investigation of animal diseases is followed and clarify and document how it will respond to emerging diseases. USDA generally agreed with GAO’s recommendations.³²

iii. Air Travel

On December 16, 2015, GAO released a report entitled, “Air Travel and Communicable Diseases: Comprehensive Federal Plan Needed for U.S. Aviation System’s Preparedness.” The

³¹ U.S. Gov’t Accountability Office, *Biosurveillance: DHS Should Not Pursue BioWatch Upgrades or Enhancements Until System Capabilities are Established* (Oct. 2015) (GAO-16-99).

³² U.S. Gov’t Accountability Office, *Emerging Animal Diseases: Actions Needed to Better Position USDA to Address Future Risks* (Dec. 2015) (GAO-16-132).

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GAO found that all of the airports and airlines that they reviewed during this study have plans in place for responding to communicable disease threats. However, the United States does not have a comprehensive national aviation-preparedness plan that would prevent and contain the spread of diseases from air travel. There is not a requirement for U.S. airports and airlines to have preparedness plans, therefore it is unknown which airports and airlines have existing plans. While conducting this study, GAO spoke with aviation stakeholders who flagged challenges in responding to communicable disease threats and actions they took or would take in response; including difficulties sharing timely and accurate information about threats, training, and access to equipment that would help them control exposure to communicable diseases. As a result of their findings, GAO recommended that the U.S. Department of Transportation (DOT) work with relevant stakeholders to develop a national aviation-preparedness plan for communicable diseases. DOT agreed that a plan is needed, but suggested that public health agencies would be more appropriate to lead the effort. Despite DOT's reaction to the GAO's recommendation, GAO still believes that DOT would be the most appropriate agency to spearhead this work.³³

iv. Ebola Response

On January 6, 2016, the DHS OIG released a report entitled, "Ebola Response Needs Better Coordination, Training, and Execution." The DHS OIG found that while the DHS responded quickly to put appropriate screenings in place, there was a lack of coordination, training, and consistent screening of people entering the United States. DHS and HHS did not establish roles and responsibilities for domestic Ebola screening and as a result, there was weak coordination among the relevant agencies, personnel did not receive adequate training, and people with exposure risk may have entered into the U.S. without going through the proper screening measures. As a result of their findings, the OIG developed 10 recommendations and DHS concurred with all of them. The recommendations include but are not limited to, specific steps to improve coordination with relevant agencies, providing guidance and resources to ports of entry, revising training requirements, and updating guidance and screening procedures. The OIG considers 7 of their recommendations resolved and closed, but 3 recommendations require additional steps to ensure that they are properly addressed.³⁴

III. ISSUES

The following issues will be examined at the hearing:

1. The nature of the current threats against the United States and around the world, including intentional, natural, and accidental threats.
2. The lack of leadership or organization of biodefense activities and research across the Federal government.

³³ U.S. Gov't Accountability Office, *Air Travel and Communicable Diseases: Comprehensive Federal Plan Needed for U.S. Aviation System's Preparedness* (Dec. 2015) (GAO-16-127).

³⁴ U.S. Dep't of Homeland Sec., Office of Inspector General, *DHS' Ebola Response Needs Better Coordination, Training, and Execution* (Jan. 6, 2016) (OIG-16-18).

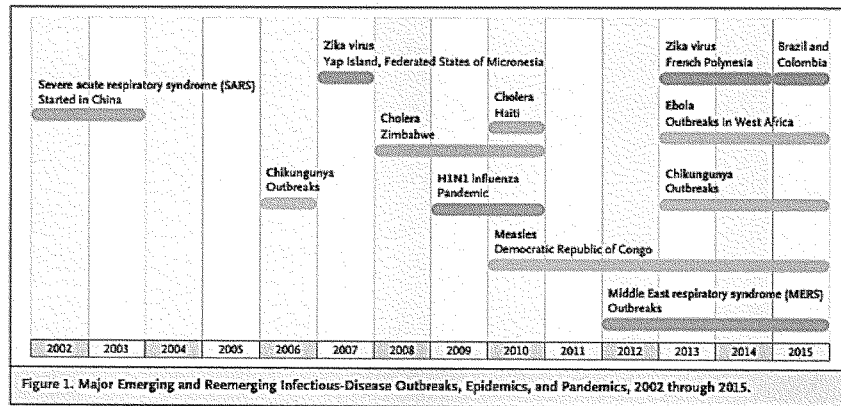
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3. The role of Federal, State, and local authorities in preparing for and responding to biological events.
4. The role of the Congress, and the Energy and Commerce Committee in particular, in shaping the response to biodefense issues.

IV. STAFF CONTACTS

If you have any questions regarding the hearing, please contact Alan Slobodin, Jen Barblan, or Brittany Havens at (202) 225-2927.

Appendix 1: Figure 1 From Sands, *et al.*, *The Neglected Dimension of Global Security—A Framework for Countering Infectious Disease Crises*, NEW ENGLAND J. OF MEDICINE (Jan. 13, 2016)



Appendix 2: Excerpt from Gryphon Scientific, *Risk and Benefit Analysis of Gain of Function Research* 850 (Dec. 2015)

16.8 Terrorist and Extremist Events Tied to Biological Warfare

| Table 16.3. Chronology of terrorist and extremist events tied to biological warfare (BW) | | |
|--|---|--|
| Date of event (most recent to oldest) | Group | Description of event |
| August 28, 2014 | Islamic State of Iraq and the Levant (ISIL, ISIS, Daesh) | <i>Foreign Policy</i> journalists report on the obtained contents of one alleged ISIL member's laptop. ²⁴⁰² It held over 35,000 files dedicated to Jihad, a few of which discussed BW. ²⁴⁰³ |
| 2013 | Communist Party of the Philippines/ New People's Army (CPP/NPA) | Philippines military claims that NPA used feces to spike explosive devices to cause sepsis, in what appears to be a modern take on the Viet Cong punji stick technique. ²⁴⁰⁴ The NPA denies this. ²⁴⁰⁵ |
| May 2012 | Revolutionary Armed Forces of Colombia (FARC) | A defused FARC gas cylinder bomb reportedly had feces mixed with shrapnel in order to cause sepsis upon injury. ²⁴⁰⁶ |

²³⁹⁹ Ibid.

²³⁹⁸ Ibid.

²³⁹⁹ Ibid.

²⁴⁰⁰ Ibid.

²⁴⁰¹ Ibid.

²⁴⁰² Harald Doornbos, Jenan Moussa, "Found: The Islamic State's Terror Laptop of Doom," *Foreign Policy*, August 28, 2014, <http://foreignpolicy.com/2014/08/28/Found-the-islamic-states-terror-laptop-of-doom/>. Accessed June 30, 2015.

²⁴⁰³ Ibid.

²⁴⁰⁴ "Philippine Army finds human feces, snake venom in wounded soldiers' wounds," *Nindanao Examiner*, September 4, 2013, <http://mindanaoexaminer.com/philippine-army-finds-human-feces-snake-venom-in-wounded-soldiers-wounds/>. Accessed June 30, 2015.

²⁴⁰⁵ Ibid.

²⁴⁰⁶ "Army destroys minefield in southwest Colombia," *Colombia Reports*, May 17, 2012, <http://colombiareports.com/minefield-and-explosives-found-in-southwest-colombia/>. Accessed August 11, 2015.

Appendix 2: Excerpt from Gryphon Scientific, *Risk and Benefit Analysis of Gain of Function Research* 850 (Dec. 2015)

Table 16.3. Chronology of terrorist and extremist events tied to biological warfare (BW)

| Date of event (most recent to oldest) | Group | Description of event |
|---|---|--|
| 2010 | "Indian Mujahedeen (Assam)" | A 2010 email claiming to be from the "Indian Mujahedeen (Assam)" group threatens biological warfare against India unless its demands are met. ²⁴⁰⁷ However, no evidence exists that this group had or has a BW capability. |
| After 2009, up to 2011 | Al Qaeda (AQ Central) | Senior AQ member Abu-Salih al Somali authors "Terror Franchise: The Unstoppable Assassin, TECHS Vital role for its success" sometime after 2009. ²⁴⁰⁸ The document ends with a detailed list of military topics about which the author is requesting the "techs" to research and share instruction manuals and videos. BW topics figure prominently on this list, and are marked as " <u>immediately needed</u> ." ²⁴⁰⁹ The document is captured in the 2011 raid that killed Bin Laden. ²⁴¹⁰ |
| 2009 | Al Qaida in the Islamic Maghreb (AQIM) | Highly contested news reports of a BW training camp accident. ^{2411,2412,2413} |

²⁴⁰⁷ "Extremists Warn of Biological Strike in India," *Nuclear Threat Initiative Global Security Newswire*, October 4, 2010, <http://www.nti.org/gsn/article/extremists-warn-of-biological-strike-in-india/>. Accessed June 30, 2015.

²⁴⁰⁸ David Francis, "Al Qaeda's Blueprint For How To Start a Homegrown Terror Franchise," *Foreign Policy*, May 20, 2015, <http://foreignpolicy.com/2015/05/20/al-qaedas-blueprint-for-how-to-start-a-homegrown-terror-franchise/>. Accessed June 30, 2015.

²⁴⁰⁹ Office of the Director of National Intelligence, Bin Laden's Bookshelf," <http://www.dni.gov/index.php/resources/bin-laden-bookshelf?start=1>. Retrieved under the "Now Declassified Material" folder: Abu-Salih Al Somali, "Terror Franchise: The Unstoppable Assassin, TECHS Vital role for its success," p. 2, 5, 10, <http://www.dni.gov/files/documents/ubl/english/Terror%20Franchise.pdf>. Accessed June 30, 2015.

²⁴¹⁰ Ibid.

²⁴¹¹ For a critical review of these accounts, see: René Pita, Rohan Gunaratna, Philip Henika, "Al Qaeda in the Islamic Maghreb (AQIM) and the Alleged Production of the Etiological Agent of Plague," *ASA Newsletter* 131 (April 2009): p. 1, 21-22, <http://www.asanltr.com/newsletter/09-2/articles/092a.pdf>. Accessed July 17, 2015.

²⁴¹² For the accounts themselves, see:

Eli Lake, "Al Qaeda bungles arms experiment," *The Washington Times*, January 19, 2009, <http://www.washingtontimes.com/news/2009/jan/19/al-qaeda-bungles-arms-experiment/>. Accessed July 14, 2015. And:

²⁴¹³ Olivier Guitta, "Al-Qaeda in the Islamic Maghreb: A Threat for the West," *Defence Against Terrorism Review* 3, no. 1 (Spring 2010): p. 57-58, http://www.coedat.nato.int/publication/datr/volume5/03-Al-Qaeda_in_the_Islamic_Maghreb_A_Threat_for_the_West.pdf. Accessed July 14, 2015.

Appendix 2: Excerpt from Gryphon Scientific, *Risk and Benefit Analysis of Gain of Function Research* 850 (Dec. 2015)

| Table 16.3. Chronology of terrorist and extremist events tied to biological warfare (BW) | | |
|--|-------------------------------|--|
| Date of event (most recent to oldest) | Group | Description of event |
| July 17, 2008 | [Aafia Siddiqui alleged case] | The FBI's complaint filing against Aafia Siddiqui during her trial stated that at the time of Aafia Siddiqui's arrest on July 17, 2008, Afghanistan National Police found "numerous chemical substances in gel and liquid form that were sealed in glass bottles and glass jars," as well as "numerous documents describing the creation of explosives, chemical weapons, and other weapons involving biological material and radiological agents," "documents detailing United States military assets" personal papers including "descriptions of various landmarks in the United States, including in New York City," and "handwritten notes that referred to a 'mass casualty attack'" and that listed various locations in the United States, including Plum Island, the Empire State Building, the Statue of Liberty, Wall Street, and the Brooklyn Bridge." ²⁴¹⁴ The government's sentencing submission for the case also holds that her "thumb drive contained documents [...] including: [...] discussions of the construction of chemical and biological weapons." ²⁴¹⁵ The prosecution argued that Aafia Siddiqui's "conduct was the very definition of a federal crime of terrorism." ²⁴¹⁶ The media reported to the effect that she was a "suspected al-Qaeda operative;" Siddiqui and her family deny this allegation, and her trial did not involve an assessment of this accusation. ^{2417,2418,2419,2420,2421} Since then, the Taliban, the Tehrik-i-Taliban Pakistan, Al Qaeda, and most recently ISIL have offered (some on multiple occasions) to trade Siddiqui against hostages. ^{2422,2423,2424,2425,2426,2427} |

- ²⁴¹⁴ Plum Island is the site of the Plum Island Animal Disease Center, although the prosecution did not elaborate on the alleged targets. United States District Court Southern District of New York, *United States of America v. Aafia Siddiqui* (defendant), "Sealed Complaint: Violations of 18 U.S.C. §§ 111, 1114, p. 1-3, <http://www.justice.gov/archive/opa/pr/2008/August/siddiqui-aafia-complaint.pdf>. Accessed June 30, 2015.
- ²⁴¹⁵ United States District Court Southern District of New York, *United States of America v. Aafia Siddiqui* (defendant), "Government's Sentencing Submission," Attorney for the United States of America: Preet Bharara, United States Attorney for the Southern District of New York, Assistant United States Attorneys of Counsel, Christopher L. LaVigne, David M. Rody, Jenna M. Dabbs, Case 1:08-cr-00826-RMB, Document 250, Filed August 29, 2010. http://web.archive.org/web/20120314163620/http://www.nefafoundation.org/miscellaneous/US_v_Siddiqui_usgsentmemo.pdf. Accessed June 30, 2015.
- ²⁴¹⁶ Ibid.
- ²⁴¹⁷ "Dr. Aafia to boycott trial," *The Nation*, November 21, 2009, <http://nation.com.pk/Politics/21-Nov-2009/Dr-Aafia-to-boycott-trial>. Accessed June 30, 2015.
- ²⁴¹⁸ Benjamin Weiser, "Indictment Hints of Plan to Attack Landmarks," *The New York Times*, September 2, 2008, http://www.nytimes.com/2008/09/03/nyregion/03indict.html?_r=1&.
- ²⁴¹⁹ Petra Bartosiewicz, "Al-Qaeda Woman? Putting Aafia Siddiqui on Trial," *Time*, January 18, 2010, <http://content.time.com/time/nation/article/0,8599,1954598,00.html>.
- ²⁴²⁰ Juliane von Mittelstaedt, "America's Most Wanted: 'The Most Dangerous Woman in the World,'" *Spiegel Online*, November 27, 2008, <http://www.spiegel.de/international/world/america-s-most-wanted-the-most-dangerous-woman-in-the-world-a-593195-druck.html>.
- ²⁴²¹ "Federal jury convicts Pakistani woman of attempted murder of US personnel," *Jurist*, February 4, 2010, <http://jurist.org/paperchase/2010/02/federal-jury-convicts-pakistani-woman.php>.
- ²⁴²² Mushtaq Yusufzai, "Taliban to execute US soldier if Aafia not released," *The News*, February 5, 2010, http://www.webcitation.org/query?url=http%3A%2F%2Fwww.thenews.com.pk%2Ftop_story_detail.asp%3Fid%3D27072.
- ²⁴²³ Bill Roggio, "Zawahiri claims al Qaeda is holding US citizen hostage," *Long War Journal Threat Matrix*, December 1, 2011, https://web.archive.org/web/20150103043251/http://www.longwarjournal.org/threat-matrix/archives/2011/12/zawahiri_claims_al_qaeda_holdi.php.
- ²⁴²⁴ "Taliban confirm they have Swiss hostages," *Agence France Presse*, July 29, 2011, retrieved at *The Express Tribune*: <http://tribune.com.pk/story/220022/tehrrik-i-taliban-say-they-have-swiss-hostages/>.

Appendix 2: Excerpt from Gryphon Scientific, *Risk and Benefit Analysis of Gain of Function Research* 850 (Dec. 2015)

| Table 16.3. Chronology of terrorist and extremist events tied to biological warfare (BW) | | |
|--|---|---|
| Date of event (most recent to oldest) | Group | Description of event |
| 2008 | East Turkistan Islamic Movement | The Chinese government alleges that Emeti Yakuf, an alleged terrorist connected to the East Turkistan Islamic Movement, threatened to use biological and chemical weapons to disrupt the 2008 Olympics held in China, and that he trained group members on making poisons. ²⁴²⁸ This individual was reportedly killed in a 2012 U.S. drone strike in Pakistan. ²⁴²⁹ |
| June 27, 2006 | Al-Aqsa Martyrs Brigade | The group issues a statement claiming that they possess chemical and biological weapons, in an attempt to deter Israeli military action. ²⁴³⁰ This claim is regarded as spurious. ²⁴³¹ |
| April 4, 2003 | Ansar al-Islam (AAI) | MSNBC reporters state that their initial field tests for botulinum and ricin toxins came up positive at a site in Iraq used by the group, but that no <i>B. anthracis</i> was detected; then-Secretary of State Colin Powell had previously said the camp held a poison laboratory. ²⁴³² However, in retrospect, the site does not appear to have produced toxins. The site is not mentioned in the report of the Iraq Survey Group. ²⁴³³ |
| August 2003 | Jemaah Islamiyah | Arrest of Riduan Isamuddin, the director of operations for Jemaah Islamiyah who organized for Yazid Sufaat's transfer to AQ. ^{2434,2435} |
| June 2002 | Revolutionary Armed Forces of Colombia (FARC) | A defused FARC gas cylinder bomb reportedly had feces mixed with shrapnel in order to cause sepsis upon injury. ²⁴³⁶ |

²⁴²⁵ Nima Elbagir, Ingrid Formanek, "Malian troops take key town; humanitarian crisis grows," *CNN*, January 21, 2013, <http://www.cnn.com/2013/01/21/world/africa/mali-unrest/>.

²⁴²⁶ Jan Lopatka, ed. Alison Williams, "Video of kidnapped Czechs demands release of jailed Pakistani," *Reuters*, June 26, 2013, <http://www.reuters.com/article/2013/06/26/us-pakistan-czech-kidnapping-idUSBRE95P0XJ20130626>.

²⁴²⁷ James Fielding, Marco Giannangeli, "British Aid Worker Executed By Taliban," *Daily Express*, October 10, 2013, <http://web.archive.org/web/20101015002351/http://www.dailyexpress.co.uk/posts/view/204533/British-aid-worker-executed-by-Taliban>.

²⁴²⁸ "'Eastern Turkistan' terrorists identified," *China Daily*, October 21, 2008, http://www.chinadaily.com.cn/china/2008-10/21/content_7126503.htm.

²⁴²⁹ Declan Walsh, Eric Schmitt, "Militant Leader Believed Dead in Pakistan Drone Strike," *The New York Times*, August 24, 2012, http://www.nytimes.com/2012/08/25/world/asia/us-drone-strikes-kill-18-in-pakistan.html?_r=1.

²⁴³⁰ "Al-Aqsa Martyrs Brigade in Palestine Claims to Have Developed Chemical and Biological Weapons and Threatens Their Use in Israel," *SITE Monitoring Service Enterprise*, June 27, 2006, <https://ent.siteintelgroup.com/Jihadist-News/6-27-06-al-aqsa-martyrs-in-palestine-creates-wmd.html>.

²⁴³¹ Michael Moodie, Markus Binder, "Jihadists and Chemical Weapons," *Jihadists and Weapons of Mass Destruction*, eds. Gary Ackerman, Jeremy Tamsett (Boca Raton: CRC Press, 2009), p. 143.

²⁴³² Preston Mendenhall, "Positive test for terror toxins in Iraq," *MSNBC.com*, April 4, 2003, http://www.nbcnews.com/id/3070394/ns/world_news/t/positive-test-terror-toxins-iraq/#.VXdWckbrJ-A.

²⁴³³ Milton Leitenberg, *Assessing the Biological Weapons and Bioterrorism Threat*, Strategic Studies Institute monograph, December 2005, p. 26-27, <http://www.strategicstudiesinstitute.army.mil/pdffiles/pub639.pdf>.

²⁴³⁴ Joel Roberts, "Thailand PM: Hambali Was Plotting," *CBS News*, August 17, 2003, <http://www.cbsnews.com/news/thailand-pm-hambali-was-plotting/>.

²⁴³⁵ Rolf Mowatt-Larssen, "Al Qaeda Weapons of Mass Destruction Threat: Hype or Reality?" Paper, Harvard Kennedy School Belfer Center for Science and International Affairs, January 2010, p. 28, http://belfercenter.ksg.harvard.edu/publication/19852/al_qaeda_weapons_of_mass_destruction_threat.html.

²⁴³⁶ Mariano C. Bartolome, Maria Jose Espona, "Chemical and Biological Terrorism in Latin America: The Revolutionary Armed Forces of Colombia," *The ASA Newsletter* 03-5, no. 98 (October 31, 2003), <http://www.asanltr.com/newsletter/03-5/articles/035c.htm>.

Appendix 2: Excerpt from Gryphon Scientific, *Risk and Benefit Analysis of Gain of Function Research* 850 (Dec. 2015)

| Table 16.3. Chronology of terrorist and extremist events tied to biological warfare (BW) | | |
|--|---|---|
| Date of event (most recent to oldest) | Group | Description of event |
| December 2001 | Al Qaeda (AQ Central); Jemaah Islamiyah | Rauf Ahmed is detained in Pakistan, and Yazid Sufaat is arrested in Malaysia. ^{2437,2438} Pakistan subsequently cuts off FBI access to Rauf Ahmed in 2003; the latter is now free. ²⁴³⁹ |
| 2001 | Jemaah Islamiyah | Yazid Sufaat flees Afghanistan for Bogor, Indonesia, to escape from the October 2001 U.S. intervention. ²⁴⁴⁰ He reportedly seeks to set up a new BW program in-country upon arrival, but fails to recruit a microbiologist at an Indonesian institute. ^{2441,2442,2443} |
| September and October 2001 | [Amerithrax case] | "At least five envelopes containing significant quantities of <i>Bacillus anthracis</i> " were mailed to U.S. targets. ²⁴⁴⁴ The attacks killed five and sickened seventeen other individuals. ²⁴⁴⁵ FBI concluded that Bruce E. Ivins, a researcher at USAMRIID (U.S.A.) had sent the letters. ²⁴⁴⁶ |
| 1999-2001 | Al Qaeda (AQ Central); Jemaah Islamiyah | Zawahiri launches a BW program in 1999, and hires Rauf Ahmed. ^{2447,2448} Ahmed establishes a covert laboratory in Afghanistan. ²⁴⁴⁹ By 2000, Zawahiri recruits Yazid Sufaat. ²⁴⁵⁰ U.S. outing of the Taliban disrupts the plan and the laboratory is discovered. ^{2451,2452} |
| 1998 to May 2000 | "Palestinian Group" | A Palestinian group (unknown) was reportedly caught in a counterfeiting scheme whereby expired eggs contaminated with salmonella were stamped with counterfeit stamps and sold. ²⁴⁵³ Israeli news reporting on their capture in May 2000 implied that this was deliberately done to sicken Israelis. ²⁴⁵⁴ |

²⁴³⁷ Joby Warrick, "Suspect and A Setback in Al-Qaeda Anthrax Case," *The Washington Post*, October 31, 2006, <http://www.washingtonpost.com/wp-dyn/content/article/2006/10/30/AR2006103001250.html>.

²⁴³⁸ Maria Ressa, "Reports: Al Qaeda operative sought anthrax," *CNN*, October 10, 2003, <http://edition.cnn.com/2003/WORLD/asiapcf/southeast/10/10/alqaeda.anthrax/>.

²⁴³⁹ Joby Warrick, "Suspect and a Setback in Al-Qaeda Anthrax Case."

²⁴⁴⁰ Judith Miller, "U.S. Has New Concerns About Anthrax Readiness," *The New York Times*, December 28, 2003, <http://www.nytimes.com/2003/12/28/us/us-has-new-concerns-about-anthrax-readiness.html>.

²⁴⁴¹ *Ibid.*

²⁴⁴² Maria Ressa, "Reports: Al Qaeda operative sought anthrax."

²⁴⁴³ René Pita, Rohan Gunaratna, "Revisiting Al-Qa'ida's Anthrax Program,"

²⁴⁴⁴ The United States Department of Justice, "Amerithrax Investigative Summary, Released Pursuant to the Freedom of Information Act," February 19, 2010, p. 1, <http://www.justice.gov/archive/amerithrax/docs/amx-investigative-summary.pdf>.

²⁴⁴⁵ *Ibid.*

²⁴⁴⁶ *Ibid.*

²⁴⁴⁷ Alan Cullison, "Inside Al-Qaeda's Hard Drive," *The Atlantic*, September 2004, <http://www.theatlantic.com/magazine/archive/2004/09/inside-al-qaeda-s-hard-drive/303428/>.

²⁴⁴⁸ Rolf Mowatt-Larssen, "Al Qaeda Weapons of Mass Destruction Threat: Hype or Reality?"

²⁴⁴⁹ *Ibid.*

²⁴⁵⁰ René Pita, Rohan Gunaratna, "Revisiting Al-Qa'ida's Anthrax Program," *CTC Sentinel* Vol. 2 Issue 5, May 2009, <https://www.ctc.usma.edu/posts/revisiting-al-qaida%E2%80%99s-anthrax-program>.

²⁴⁵¹ *Ibid.*

²⁴⁵² Rolf Mowatt-Larssen, "How to Get Terrorists to Talk," *The National Interest*, February 18, 2015, p.2, <http://nationalinterest.org/feature/how-get-terrorists-talk-12270?page=2>.

²⁴⁵³ Jason Pate, Gavin Cameron, "Covert Biological Weapons Attacks against Agricultural Targets: Assessing the Impact against U.S. Agriculture," BCSIA Discussion Paper 2001-9, ESDP Discussion Paper ESDP-2001-05, John F. Kennedy School of Government, Harvard University, August 2001, p.8, http://belfercenter.ksg.harvard.edu/files/covert_biological_weapons_attacks_against_agricultural_targets.pdf.

²⁴⁵⁴ *Ibid.*

Appendix 2: Excerpt from Gryphon Scientific, *Risk and Benefit Analysis of Gain of Function Research* 850 (Dec. 2015)

| Table 16.3. Chronology of terrorist and extremist events tied to biological warfare (BW) | | |
|--|--|---|
| Date of event (most recent to oldest) | Group | Description of event |
| February 1999 | Chechen group under Salman Raduyev | One Russian newspaper claimed that Salman Raduyev, a prominent Chechen leader, had threatened to steal biological weapons from ex-Soviet biological warfare laboratories unless the government released two captured women. ²⁴⁵⁵ This report could not be verified. ²⁴⁵⁶ |
| June 1998 | "Republic of Texas" | Two members of the group sent emails threatening to use biological agents against federal officials; no biological agents were uncovered at the time of their arrest. ²⁴⁵⁷ |
| April 1998 | Palestinian Islamic Jihad | A Jordanian newspaper cites a leading figure in the organization as having discussed the possibility of using BW. ²⁴⁵⁸ This remains unconfirmed. |
| March 6, 1998 | National Liberation Army (ELN) | The ELN detonate an explosive device reportedly spiked with fecal matter to cause sepsis upon injury. ²⁴⁵⁹ |
| 1997 | Counter Holocaust Lobbyists of Hillel | Agar and <i>B. cereus</i> in a petri dish apparently labelled " <i>anthracis</i> " [SIC] and " <i>Yersinia</i> " was sent to a Jewish organization in Washington. ²⁴⁶⁰ Whether this was an anthrax hoax or the group thought the package contained <i>B. anthracis</i> is not known; the package contained a hate letter that further misidentified the petri dish as containing a "chemical warfare" agent. ²⁴⁶¹ |
| 1996 | "Justice Department" [animal rights radical group] | A group calling itself the "Justice Department" mails razors to fur retailers in Canada in 1996 which they claim are covered with HIV-infected blood; whether they really did so is not known. ²⁴⁶² |
| March 15, 1995 | Aum Shinrikyo | The group ineffectually attempts to disperse botulinum toxin from three sprayer-suitcases in the Kasumigaseki metro station (Japan). ²⁴⁶³ |
| November 4, 1994 | Aum Shinrikyo | The group fails in an assassination attempt involving botulinum toxin mixed with juice. ²⁴⁶⁴ |

²⁴⁵⁵ W. Seth Carus, *Bioterrorism and Biocrimes: The Illicit Use of Biological Agents Since 1900*, Working Paper (Washington: Center for Counterproliferation Research, National Defense University, February 2001 Revision), p. 107.

²⁴⁵⁶ Ibid.

For instance, the Russian think-tank PIR Center does not include this incident in their list of North Caucasus CBRN threat events. PIR Center, "WMD Terrorism Originated in North Caucasus: Again on the Agenda?" *PIR Center Report*, April 26, 2013, <http://www.pircenter.org/en/articles/1312-wmd-terrorism-originated-in-north-caucasus-again-on-the-agenda>.

²⁴⁵⁷ W. Seth Carus, *Bioterrorism and Biocrimes: The Illicit Use of Biological Agents Since 1900*, p. 108-109, p. 186.

²⁴⁵⁸ Ibid.

²⁴⁵⁹ Mariano C. Bartolome, Maria Jose Espona, "Chemical and Biological Terrorism in Latin America: The Revolutionary Armed Forces of Colombia."

²⁴⁶⁰ W. Seth Carus, *Bioterrorism and Biocrimes: The Illicit Use of Biological Agents Since 1900*, p. 110-111; The B'nai B'rith International Jewish Monthly, Volume 111, (1996), p. 67, <https://books.google.com/books?id=V--3AAAAIAAJ&q=anthracis+Yersinia+Counter+Holocaust+Lobbyists+of+Hillel&dq=anthracis+Yersinia+Counter+Holocaust+Lobbyists+of+Hillel&hl=en&sa=X&ved=0CC8Q6AEwA2oVChMI98TMwLKlXgIVOEaMCh0gNAC0>.

²⁴⁶¹ W. Seth Carus, *Bioterrorism and Biocrimes: The Illicit Use of Biological Agents Since 1900*, p. 111.

²⁴⁶² Ibid.

²⁴⁶³ Richard Danzig, Marc Sageman, Terrance Leighton, Lloyd Hough, Hidemi Yuki, Rui Kotani, Zachary M. Hosford, "Aum Shinrikyo: Insights into how terrorists develop biological and chemical weapons, second edition," Center for a New American Security, December 2012, p. 21, http://www.cnas.org/files/documents/publications/CNAS_AumShinrikyo_SecondEdition_English.pdf.

²⁴⁶⁴ Ibid.

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Table 16.3. Chronology of terrorist and extremist events tied to biological warfare (BW)

| Date of event (most recent to oldest) | Group | Description of event |
|---|---|---|
| 1993 | Animal Liberation Front (ALF) [animal rights radical group] | A spokesman for the Animal Liberation Front (ALF) claims that bombs planted in the U.K. by members of the collective had been purposefully tainted with HIV, but authorities dismiss this account. ²⁴⁶⁵ |
| November 18, 1993 | Aum Shinrikyo | The group disperses 20 liters of botulinum toxin slurry from a car sprayer in a failed assassination attempt. ²⁴⁶⁶ |
| 1993 | Aum Shinrikyo | Following failed attacks with the liquid product, the group sets up a (crude) dry production line for <i>B. anthracis</i> . ²⁴⁶⁷ |
| July-August 1993 | Aum Shinrikyo | The group produces some 10 to 20 tons of slurry containing <i>B. anthracis</i> (perhaps not pathogenic), which are then ineffectually released from spray trucks in some 10 to 20 attacks. ²⁴⁶⁸ |
| May-June 1993 | Aum Shinrikyo | The group produces roughly 20 tons of slurry containing <i>B. anthracis</i> (perhaps not pathogenic), and ineffectually sprays the product from the roof of one of its facilities. ²⁴⁶⁹ |
| 1992 | Aum Shinrikyo | The group sets up a (crude) liquid production line for <i>B. anthracis</i> . ²⁴⁷⁰ |
| March-July 1990 | Aum Shinrikyo | The group produces several hundred tons of slurry as part of their botulinum toxin production program. ²⁴⁷¹ They disseminate this material in 20 to 40 different attempted attacks in this time period, all without success. ²⁴⁷² |
| Spring 1990 | Aum Shinrikyo | Seiichi Endo, the leader of the group's BW program, harvests <i>C. botulinum</i> from soil in Japan. ²⁴⁷³ |
| September 1984 | Rajneeshees | <i>S. typhimurium</i> is used to contaminate at least 10 restaurant salad bars in The Dalles, Oregon (U.S.A.), causing at least 751 people to fall ill. ^{2474,2475,2476} |

²⁴⁶⁵ W. Seth Carus, *Bioterrorism and Biocrimes: The Illicit Use of Biological Agents Since 1900*, p. 76.

²⁴⁶⁶ Richard Danzig et al., "Aum Shinrikyo: Insights into how terrorists develop biological and chemical weapons, second edition,"

²⁴⁶⁷ Ibid.

²⁴⁶⁸ Ibid.

²⁴⁶⁹ Ibid.

²⁴⁷⁰ Ibid.

²⁴⁷¹ Richard Danzig et al., "Aum Shinrikyo: Insights into how terrorists develop biological and chemical weapons, second edition," *Center for a New American Security*, December 2012, p. 20,

http://www.cnas.org/files/documents/publications/CNAS_AumShinrikyo_SecondEdition_English.pdf.

²⁴⁷² Ibid.

²⁴⁷³ Richard Danzig et al., "Aum Shinrikyo: Insights into how terrorists develop biological and chemical weapons, second edition," *Center for a New American Security*, December 2012, p. 18-20,

http://www.cnas.org/files/documents/publications/CNAS_AumShinrikyo_SecondEdition_English.pdf.

²⁴⁷⁴ Thomas J. et. al (1997), "A Large Community Outbreak of Salmonellosis Caused by Intentional Contamination of Restaurant Salad Bars," *Journal of the American Medical Association* 278, no. 5,

http://www.cdc.gov/php/docs/forensic_epidemiology/Additional%20Materials/Articles/Torok%20et%20al.pdf;

²⁴⁷⁵ W. Seth Carus, "The Rajneeshees (1984)," *Toxic Terror: Assessing Terrorist Use of Chemical and Biological Weapons*, ed. Jonathan Tucker (Cambridge: The MIT Press, 2001), p. 115;

²⁴⁷⁶ W. Seth Carus, "Rajneeshees," *Encyclopedia of Bioterrorism Defense, 2nd Edition*, eds. Rebecca Katz, Raymond A. Zilinskis (Hoboken: John Wiley & Sons, 2011), p. 383-384.

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| Table 16.3. Chronology of terrorist and extremist events tied to biological warfare (BW) | | |
|--|----------------------------------|--|
| Date of event (most recent to oldest) | Group | Description of event |
| August 29, 1984 | Rajneeshees | Two Wasco County commissioners were given water deliberately tainted with <i>S. typhimurium</i> by Rajneeshees; both fell ill. ²⁴⁷⁷ |
| Early 1984 | Rajneeshees | Reports, based on admissions made by Rajneesh members, of other cult BW attacks prior to August 1984. ²⁴⁷⁸ These are unconfirmed because none of the attacks were successful and because there may have been a desire to exaggerate wrongdoings by one of the chief organizers (Puja), who was hated. ²⁴⁷⁹ |
| October 14, 1981 | Dark Harvest [eco-radical group] | In an apparent follow-on to the October 10, 1981 incident described below, British police received an anonymous tip that led them to a metal box allegedly containing <i>B. anthracis</i> . ²⁴⁸⁰ However, unlike in the October 10 incident, the soil did not contain <i>B. anthracis</i> . ²⁴⁸¹ |
| October 10, 1981 | Dark Harvest [eco-radical group] | The eco-radical group "Dark Harvest" took <i>B. anthracis</i> -contaminated soil from Gruinard Island (a then-contaminated British military WWII site used to test <i>B. anthracis</i> bombs) and spread it on the grounds of Porton Down in 1981 (Britain's main biodefense and chemical warfare defense establishment, and previously the center orchestrating Britain's biological weapons program). ²⁴⁸² The soil did contain <i>B. anthracis</i> . ²⁴⁸³ |
| 1980s | Tamil "militants" | A single unconfirmed account of Tamil "militants" threatening biological warfare. ²⁴⁸⁴ |
| October 1980 | Red Army Faction | The German-based, now-defunct, Red Army Faction (RAF) reportedly maintained a botulinum toxin laboratory in Paris, France until it was uncovered in October 1980. ²⁴⁸⁵ A recent review of this case has cast doubt on parts of the underlying story, however, and German authorities apparently remain convinced that "no evidence whatsoever [exists] that members of the 'RAF' had planned or prepared an attack using biological agents." ^{2486,2487} |

²⁴⁷⁷ W. Seth Carus, "Rajneeshees," p. 534.

²⁴⁷⁸ *Ibid.*, p. 534-535.

²⁴⁷⁹ W. Seth Carus, *Bioterrorism and Biocrimes: The Illicit Use of Biological Agents Since 1900*, p. 534.

²⁴⁸⁰ *Ibid.*

²⁴⁸¹ *Ibid.*

²⁴⁸² W. Seth Carus, *Bioterrorism and Biocrimes: The Illicit Use of Biological Agents Since 1900*, p. 58.

²⁴⁸³ *Ibid.*

²⁴⁸⁴ *Ibid.*

²⁴⁸⁵ W. Seth Carus, *Bioterrorism and Biocrimes: The Illicit Use of Biological Agents Since 1900*, p. 156-157.

²⁴⁸⁶ *Ibid.*

²⁴⁸⁷ The review in question is:

Terence Taylor, Tim Trevan, "The Red Army Faction (1980)," *Toxic Terror: Assessing Terrorist Use of Chemical and Biological Weapons*, ed. Jonathan B. Tucker (Cambridge: MIT Press, 2000),

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Table 16.3. Chronology of terrorist and extremist events tied to biological warfare (BW)

| Date of event (most recent to oldest) | Group | Description of event |
|---|---|--|
| February 1975 | POLISARIO; Basque Fatherland and Liberty (ETA) | One unconfirmed report of a February 1975 offer by a group called POLISARIO to coordinate poisoning of water supplies. ²⁴⁸⁸ Even if POLISARIO did make such a threatening offer, no evidence exists that POLISARIO sought a BW capability. ^{2489,2490} |
| January 18, 1972 | R.I.S.E. | Arrest of two R.I.S.E. founders for having reportedly planned to contaminate Chicago's municipal water system with <i>Salmonella typhi</i> (causative agent of typhoid fever). ²⁴⁹¹ |

16.9 Designated Foreign Terrorist Organizations and Biological Weapons

Table 16.4. Currently designated Foreign Terrorist Organizations and BW

| Designated Foreign Terrorist Organizations ²⁴⁹² | Publicly threatened BW? | Historically had a BW program? ²⁴⁹³ | BW efforts believed ongoing? | Notes |
|--|-------------------------------|--|------------------------------------|---|
| Abu Nidal Organization (ANO) | NO | NO | | |
| Abu Sayyaf Group (ASG) | NO | NO | | A single news report that police captured publicly-available reading material on biological and chemical warfare during the capture of six suspected group members. ²⁴⁹⁴ Whether the group members were members of ASG or JI is unclear. |
| Aum Shinrikyo (AUM) | NO | YES | NO | Attempted production of BW agent; launched failed BW attacks. See the detailed entry below. Leadership and BW-program members captured. |
| Basque Fatherland and Liberty (ETA) | NO | NO | | One unconfirmed report of a February 1975 offer by a group called Polisario to coordinate poisoning of water supplies. ²⁴⁹⁵ |

²⁴⁸⁸ W. Seth Carus, *Bioterrorism and Biocrimes: The Illicit Use of Biological Agents Since 1900*, p. 121.

²⁴⁸⁹ POLISARIO stands for "Frente Popular para la Liberacion de Saquia el-Hamra y Rio de Oro," and is a group that seeks to overthrow Moroccan control of Western Sahara and create an independent state for Sahrawi tribes based on Islamic culture.

²⁴⁹⁰ Gail H. Nelson, "POLISARIO," *Encyclopedia of Bioterrorism Defense*, 2nd Edition, eds. Rebecca Katz, Raymond A. Zilinskas (Hoboken: John Wiley & Sons, 2011), p. 510-512.

²⁴⁹¹ W. Seth Carus, "RISE: A Case Study," *Encyclopedia of Bioterrorism Defense*, 2nd Edition, eds. Rebecca Katz, Raymond A. Zilinskas (Hoboken: John Wiley & Sons, 2011), p. 542.

²⁴⁹² U.S. Department of State, "Foreign Terrorist Organizations," <<http://www.state.gov/j/ct/rls/other/des/123085.htm>>.

²⁴⁹³ Where a "BW program" is defined as a military program for the production of a biological pathogen.

²⁴⁹⁴ Christian Enemark, *Disease and Security: Natural plagues and biological weapons in East Asia* (Abingdon: Routledge, 2007), p. 106.

²⁴⁹⁵ W. Seth Carus, *Bioterrorism and Biocrimes: The Illicit Use of Biological Agents Since 1900*, Working Paper (Washington: Center for Counterproliferation Research, National Defense University, February 2001 Revision), p. 121.

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| Table 16.4. Currently designated Foreign Terrorist Organizations and BW | | | | |
|--|--------------------------------|--|--|--|
| Designated Foreign Terrorist Organizations²⁴⁹² | Publicly threatened BW? | Historically had a BW program?²⁴⁹³ | BW efforts believed ongoing? | Notes |
| Gama'a al-Islamiyya (Islamic Group) (IG) | NO | NO | | |
| Hamas | NO | NO | | Reported interest in chemical poisons. ²⁴⁹⁶ |
| Harakat ul-Mujahidin (HUM) | NO | NO | | |
| Hizballah | NO | NO | | |
| Kahane Chai (Kach) | NO | NO | | |
| Kurdistan Workers Party (PKK) (Kongra-Gel) | NO | NO | | A single unconfirmed Turkish newspaper report of Cobra poison smuggling for profit. ²⁴⁹⁷ |
| Liberation Tigers of Tamil Eelam (LTTE) | Unconfirmed | NO | NO | A single unconfirmed account of Tamil "militants" threatening biological warfare in the 1980s. ²⁴⁹⁸ Report of LTTE use of chlorine for chemical warfare. ²⁴⁹⁹ Group has been defeated. |
| National Liberation Army (ELN) | NO | NO, albeit reported war use of biological material | Unknown if continuing war use of biological material | Reports that ELN used feces to spike explosive devices to cause sepsis, in what appears to be a modern take on the Viet Cong punji stick technique. ²⁵⁰⁰ |
| Palestine Liberation Front (PLF) | NO | NO | | |
| Palestinian Islamic Jihad (PIJ) | NO | NO | | A single unconfirmed April 1998 Jordanian newspaper report citing a leading figure in the organization as having discussed the possibility of using BW. ²⁵⁰¹ |
| Popular Front for the Liberation of Palestine (PFLP) | NO | NO | | |
| PFLP-General Command (PFLP-GC) | NO | NO | | |

²⁴⁹⁶ Ibid.

²⁴⁹⁷ Ibid.

²⁴⁹⁸ Ibid.

²⁴⁹⁹ James J. F. Forest, Sammy Salama, "Jihadist Tactics and Targeting," *Jihadists and Weapons of Mass Destruction*, eds. Gary Ackerman, Jeremy Tamsett (Boca Raton: CRC Press, 2009), p. 80.

²⁵⁰⁰ Mariano C. Bartolome, Maria Jose Espona, "Chemical and Biological Terrorism in Latin America: The Revolutionary Armed Forces of Colombia," *The ASA Newsletter* 03-5, no. 98 (October 31, 2003), <http://www.asanltr.com/newsletter/03-5/articles/035c.htm>.

²⁵⁰¹ W. Seth Carus, *Bioterrorism and Biocrimes: The Illicit Use of Biological Agents Since 1900*, p. 109, 186.

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| Table 16.4. Currently designated Foreign Terrorist Organizations and BW | | | | |
|---|-------------------------|--|--|---|
| Designated Foreign Terrorist Organizations ²⁴⁹² | Publicly threatened BW? | Historically had a BW program? ²⁴⁹³ | BW efforts believed ongoing? | Notes |
| Revolutionary Armed Forces of Colombia (FARC) | NO | NO, albeit reported war use of biological material | Continued war use of biological material | Reports that FARC used feces to spike explosive devices to cause sepsis, in what appears to be a modern take on the Viet Cong punji stick technique. ^{2502,2503,2504} |
| Revolutionary Organization 17 November (17N) | NO | NO | | |
| Revolutionary People's Liberation Party/Front (DHKP/C) | NO | NO | | |
| Shining Path (SL) | NO | NO | | |
| al-Qa'ida (AQ) | YES | YES | YES | Attempted production of BW agent, with unknown results. See detailed entry below. Efforts believed to be ongoing. |
| al-Qaida in the Islamic Maghreb (AQIM) | YES (by proxy with AQ) | YES | YES | By proxy with AQ (central); highly contested news reports of a BW training camp accident in 2009. ^{2505,2506,2507} |
| al-Qa'ida in the Arabian Peninsula (AQAP) | YES (by proxy with AQ) | Unknown | | Possibly by proxy with AQ (central). No information formally ties this group with AQ's BW program. The group reportedly considered contaminating U.S. food with ricin and cyanide, although no open source indications suggest the group selected this tactic for operationalization. ²⁵⁰⁸ |

²⁵⁰² Mariano C. Bartolome, Maria Jose Espona, "Chemical and Biological Terrorism in Latin America: The Revolutionary Armed Forces of Colombia".

²⁵⁰³ Pablo Esteban Parra Gallego, "IEDs: A Major Threat for a Struggling Society," *The Journal of ERW and Mine Action* 13, no. 3 (Winter 2009), <http://www.jmu.edu/cisr/journal/13.3/specialreport/gallego/gallego.shtml>

²⁵⁰⁴ "Army destroys minefield in southwest Colombia," *Colombia Reports*, May 17, 2012, <http://colombiareports.com/minefield-and-explosives-found-in-southwest-colombia/>.

²⁵⁰⁵ For a critical review of these accounts, see: René Pita, Rohan Gunaratna, Philip Henika, "Al Qaeda in the Islamic Maghreb (AQIM) and the Alleged Production of the Etiological Agent of Plague," *ASA Newsletter* 131 (April 2009): p. 1, 21-22, <http://www.asanltr.com/newsletter/09-2/articles/092a.pdf>.

²⁵⁰⁶ For the accounts themselves, see:

Eli Lake, "Al Qaeda bungles arms experiment," *The Washington Times*, January 19, 2009, <http://www.washingtontimes.com/news/2009/jan/19/al-qaeda-bungles-arms-experiment/>

²⁵⁰⁷ Olivier Guitta, "Al-Qaeda in the Islamic Maghreb: A Threat for the West," *Defence Against Terrorism Review* 3, no. 1 (Spring 2010): p. 57-58, http://www.coedat.nato.int/publication/datr/volume5/03-Al-Qaeda_in_the_Islamic_Maghreb_A_Threat_for_the_West.pdf.

²⁵⁰⁸ Mike M. Ahlers, Brian Todd, "Al Qaeda group contemplated poisoning food in U.S., officials say," December 22, 2010, <http://www.cnn.com/2010/US/12/21/al.qaeda.poison.plot/>.

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| Table 16.4. Currently designated Foreign Terrorist Organizations and BW | | | | |
|---|-------------------------|--|------------------------------|---|
| Designated Foreign Terrorist Organizations ²⁴⁹² | Publicly threatened BW? | Historically had a BW program? ²⁴⁹³ | BW efforts believed ongoing? | Notes |
| Islamic Movement of Uzbekistan (IMU) | NO | NO | | |
| Real Irish Republican Army (RIRA) | NO | NO | | |
| Jaish-e-Mohammed (JEM) | NO | NO | | |
| Lashkar-e Tayyiba (LeT) | NO | NO | | |
| Al-Aqsa Martyrs Brigade (AAMB) | YES | NO | | The group claimed to possess chemical and biological weapons in 2006 in an attempt to deter Israeli military action. ²⁵⁰⁹ This claim is regarded as spurious. ²⁵¹⁰ |
| Asbat al-Ansar (AAA) | NO | NO | | |
| Communist Party of the Philippines/New People's Army (CPP/NPA) | NO | NO, albeit reported war use of biological material | | Recent Philippines military claim that NPA used feces to spike explosive devices to cause sepsis; see FARC and ELN entries. ²⁵¹¹ The NPA denies this. |
| Jemaah Islamiya (JI) | YES (By proxy with AQ) | YES | NO | Attempted production of BW, mostly as part of Al Qaeda's program, with unknown results. See detailed entry. Group membership, including leadership and individuals involved in the BW program, decimated. |
| Lashkar i Jhangvi (LJ) | NO | NO | | Pakistani police reportedly uncovered chemical laboratories belonging to the group. ²⁵¹² |

²⁵⁰⁹ Michael Moodie, Markus Binder, "Jihadists and Chemical Weapons," *Jihadists and Weapons of Mass Destruction*, eds. Gary Ackerman, Jeremy Tamsett (Boca Raton: CRC Press, 2009), p. 143.

²⁵¹⁰ Ibid.

²⁵¹¹ "Philippine Army finds human feces, snake venom in wounded soldiers' wounds," *Nindanao Examiner*, September 4, 2013, <http://mindanaoexaminer.com/philippine-army-finds-human-feces-snake-venom-in-wounded-soldiers-wounds/>.

²⁵¹² National Consortium for the Study of Terrorism and Responses to Terrorism (START), "Terrorist Organization Profiles: Lashkar-e-Jhangvi," http://www.start.umd.edu/tops/terrorist_organization_profile.asp?id=65.

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| Table 16.4. Currently designated Foreign Terrorist Organizations and BW | | | | |
|---|-------------------------|--|------------------------------|--|
| Designated Foreign Terrorist Organizations ²⁴⁹² | Publicly threatened BW? | Historically had a BW program? ²⁴⁹³ | BW efforts believed ongoing? | Notes |
| Ansar al-Islam (AAI) | NO | Unsubstantiated reports of interest in toxins | NO | Initial reports held that the group had a poison laboratory in Iraq that manufactured botulinum and ricin toxin. ²⁵¹³ However, in retrospect, the site does not appear to have produced toxins. The site is not mentioned in the report of the Iraq Survey Group. ²⁵¹⁴ |
| Continuity Irish Republican Army (CIRA) | NO | NO | | |
| Libyan Islamic Fighting Group (LIFG) | NO | NO | | |

²⁵¹³ Preston Mendenhall, "Positive test for terror toxins in Iraq," *MSNBC.com*, April 4, 2003, http://www.nbcnews.com/id/3070394/ns/world_news/t/positive-test-terror-toxins-iraq/#.VXdWckbrJ-A.

²⁵¹⁴ Milton Leitenberg, *Assessing the Biological Weapons and Bioterrorism Threat*, Strategic Studies Institute monograph, December 2005, p. 26-27, <http://www.strategicstudiesinstitute.army.mil/pdf/files/pub639.pdf>.

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| Table 16.4. Currently designated Foreign Terrorist Organizations and BW | | | | |
|---|-------------------------|--|------------------------------|---|
| Designated Foreign Terrorist Organizations ²⁴⁹² | Publicly threatened BW? | Historically had a BW program? ²⁴⁹³ | BW efforts believed ongoing? | Notes |
| Islamic State of Iraq and the Levant (formerly al-Qa'ida in Iraq) | NO | Unknown | | Emerging group with enormous resources. Reports of chemical munitions use (chlorine, phosphine, and mustard). ^{2515,2516,2517,2518,2519} One individual member had a laptop with over 35,000 files dedicated to Jihad, a few of which discussed BW. ²⁵²⁰ Concern over alleged looting of biological laboratories in Syria. ²⁵²¹ In 2014, DHS secretary Jeh Johnson stated that his service had "seen no specific credible intelligence that ISIS is attempting to use any sort of disease or virus to attack our homeland." ²⁵²² |
| Islamic Jihad Union (IJU) | NO | NO | | |
| Harakat ul-Jihad-i-Islami/Bangladesh (HUJI-B) | NO | NO | | |
| al-Shabaab | NO | NO | | |
| Revolutionary Struggle (RS) | NO | NO | | |
| Kata'ib Hizballah (KH) | NO | NO | | |
| Harakat ul-Jihad-i-Islami (HUJI) | NO | NO | | |

²⁵¹⁵ Tom Coghlan, Catherine Philp, Ammar Shamary, "Jihadists unleash chemical weapons in battle for Tikrit," *The Times*, March 14, 2015, <<http://www.thetimes.co.uk/tto/news/world/middleeast/article4381521.ece>>.

²⁵¹⁶ "Chlorine bomb attacks by jihadists are growing threat to the UK, warns chemical warfare expert," *The Independent*, May 25, 2015, <http://www.independent.co.uk/news/uk/home-news/chlorine-bomb-attacks-by-jihadists-are-growing-threat-to-the-uk-warns-chemical-warfare-expert-10274947.html>.

²⁵¹⁷ Phosphine, chemical formula PH₃, is used as a fumigant, but is toxic if inhaled. Ibid; also see: Sajila Saseendran, "Ministry mulls banning 'killer' pesticide," *Khaleej Times*, September 2, 2014, <http://www.khaleejtimes.com/article/20140901/ARTICLE/309019899/1002>.

²⁵¹⁸ Nabih Bulos, "Islamic State confirmed to have used mustard gas against Kurds in Syria," *The Telegraph*, August 15, 2015, <http://www.telegraph.co.uk/news/worldnews/middleeast/syria/11805235/Islamic-State-confirmed-to-have-used-mustard-gas-against-Kurds-in-Syria.html>.

²⁵¹⁹ Paul Blake, "US official: 'IS making and using chemical weapons in Iraq and Syria'," *BBC News*, September 11, 2015, <http://www.bbc.com/news/world-us-canada-34211838>.

²⁵²⁰ Harald Doornbos, Jenan Moussa, "Found: The Islamic State's Terror Laptop of Doom," *Foreign Policy*, August 28, 2014, <http://foreignpolicy.com/2014/08/28/found-the-islamic-states-terror-laptop-of-doom/>.

²⁵²¹ Ari Soffer, "Experts Warn of Al Qaeda Biological Weapons Threat," *Israel National News*, October 16, 2013, <http://www.israelnationalnews.com/News/News.aspx/172897#.VXddiUbrJ-A>.

²⁵²² "Use of Ebola virus as bioterror weapon highly unlikely: Experts," *Homeland Security News Wire*, November 11, 2014, <http://www.homelandsecuritynewswire.com/dr20141111-use-of-ebola-virus-as-bioterror-weapon-highly-unlikely-experts>.

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| Table 16.4. Currently designated Foreign Terrorist Organizations and BW | | | | |
|---|-------------------------|--|------------------------------|---|
| Designated Foreign Terrorist Organizations ²⁴⁹² | Publicly threatened BW? | Historically had a BW program? ²⁴⁹³ | BW efforts believed ongoing? | Notes |
| Tehrik-e Taliban Pakistan (TTP) | NO | NO | | |
| Jundallah | NO | NO | | |
| Army of Islam (AOI) | NO | NO | | |
| Indian Mujahedeen (IM) | YES | NO | | A 2010 email claiming to be from "Indian Mujahedeen (Assam)" threatened biological warfare unless its demands were met. ²⁵²³ |
| Jemaah Anshorut Tauhid (JAT) | NO | NO | | Splinter group from Jemaah Islamiyah. |
| Abdallah Azzam Brigades (AAB) | NO | NO | | |
| Haqqani Network (HQN) | | | | |
| Ansar al-Dine (AAD) | NO | NO | | |
| Boko Haram | NO | NO | | |
| Ansaru | NO | NO | | |
| al-Mulathamun Battalion | NO | NO | | |
| Ansar al-Shari'a in Benghazi | NO | NO | | |
| Ansar al-Shari'a in Darnah | NO | NO | | |
| Ansar al-Shari'a in Tunisia | NO | NO | | |
| Ansar Bayt al-Maqdis | NO | NO | | |
| al-Nusrah Front | Unknown | Unknown | | Emerging group. Concern over alleged looting of biological laboratories in Syria. ²⁵²⁴ |
| Mujahidin Shura Council in the Environs of Jerusalem (MSC) | NO | NO | | |

²⁵²³ "Extremists Warn of Biological Strike in India," *Nuclear Threat Initiative Global Security Newswire*, October 4, 2010, <http://www.nti.org/gsn/article/extremists-warn-of-biological-strike-in-india/>.

²⁵²⁴ Ari Soffer, "Experts Warn of Al Qaeda Biological Weapons Threat."

FRED UPTON, MICHIGAN
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FOURTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115
Majority (202) 225-2827
Minority (202) 225-3641

April 5, 2016

The Honorable Donna E. Shalala
Panel Member
Blue Ribbon Study Panel on Biodefense
575 Park Avenue, Suite 901
New York, NY 10065

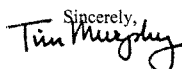
Dear Secretary Shalala:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Friday, February 12, 2016, to testify at the hearing entitled "Outbreaks, Attacks, and Accidents: Combatting Biological Threats."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Tuesday, April 19, 2016. Your responses should be mailed to Giulia Giannangeli, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to Giulia.Giannangeli@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,


Tim Murphy
Chairman
Subcommittee on Oversight and Investigations

cc: The Honorable Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Attachment

**Answer to Post-Hearing Question for the Record
Submitted to the Honorable Donna E. Shalala
from Representative Michael C. Burgess, MD, Subcommittee on Oversight and Investigations,
House Committee on Energy and Commerce**

“Outbreaks, Attacks, and Accidents: Combating Biological Threats”

February 12, 2016

The Honorable Michael C. Burgess, MD

1. As a physician, I understand that the development and validation of precise diagnostics for emerging outbreaks is crucial to combating biological threats such as Zika virus. We need to quickly develop diagnostics for these purposes and work to ensure that public health laboratories and hospital laboratories throughout the country are able to screen people for the disease and that patients have access to these tests. I'm concerned that the CDC is creating barriers for laboratories to quickly disseminate the test and by not enabling competing tests, there's no way to assess whether or not the CDC test is adequate. Please describe the process CDC engages in for sharing necessary information, test reagents, and reference materials to laboratories develop tests for emerging infectious diseases. I've also heard that despite the lack of cooperation from the CDC, some physicians have already developed tests for Zika virus at Texas Children's Hospital and Stanford University. Have you considered collaborating with these academic medical centers on developing diagnostics?

While our Study Panel is aware of the CDC process for sharing information, test reagents, and reference materials with laboratories for the purposes of developing tests for emerging infectious diseases, we do not possess sufficient information with which to describe this process in detail for you. We recommend that you obtain this information directly from the CDC.

Our Study Panel does not engage in the development of diagnostics. We do highly recommend government collaboration with academia and the private sector toward this end. The CDC and other government agencies should inform their activities with the existing expertise and progress within the U.S. biomedical enterprise. It would be better for the CDC to collaborate with academic medical centers and foster such innovation than for the CDC to operate in a vacuum, or worse, engage in unhealthy competition with the private sector.

FRED UPTON, MICHIGAN
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Majority (202) 225-2927
Minority (202) 225-3641

April 5, 2016

The Honorable James C. Greenwood
President and CEO
Biotechnology Innovation Organization
1201 Maryland Avenue, S.W., Suite 900
Washington, DC 20024

Dear Chairman Greenwood:

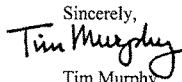
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Also attached are Member requests made during the hearing. The format of your responses to these requests should follow the same format as your responses to the additional questions for the record.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Tuesday, April 19, 2016. Your responses should be mailed to Giulia Giannangeli, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to Giulia.Giannangeli@mail.house.gov.

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Sincerely,


Tim Murphy
Chairman
Subcommittee on Oversight and Investigations

cc: The Honorable Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Attachments

**Answers to Post-Hearing Questions for the Record
and Member Requests for the Record
Submitted to the Honorable James C. Greenwood
from Representative Tim Murphy, Chairman, Representative Michael C. Burgess,
MD, and Representative Susan Brooks
Subcommittee on Oversight and Investigations
House Committee on Energy and Commerce**

“Outbreaks, Attacks, and Accidents: Combating Biological Threats”

February 12, 2016

The Honorable Tim Murphy

- 1. During the hearing, we discussed a recent GAO report on the failings of the BioWatch programs. In your view, should the Federal government continue to fund such programs in the absence of valid performance data? (Question for the Record and Member Request for the Record)**

As our Study Panel states on page 59 of our bipartisan report, *A National Blueprint for Biodefense: Leadership and Major Reform Needed to Optimize Efforts*, "The biotectors designed to inform biosurveillance of the air (commonly referred to as environmental detection) have not progressed significantly since their initial deployments... The BioWatch program was launched in 2003 with great urgency, but its potential remains unrealized. As of 2015, BioWatch uses the same technology – manual filter collection and laboratory polymerase chain reaction testing – as it did twelve years ago... The entire BioWatch system is dying for lack of innovation... To date, no fully automated, tested, and evaluated autonomous detection system has been deployed that adequately addresses the airborne biological threat or sufficiently provides operational response information."

Recommendation 31 of our report calls for the development of an environmental detection system that takes advantage of 21st Century technology. We believe that Congress should consider funding the development of advanced environmental detection systems to replace BioWatch. Ideally, we would recommend that the Secretary of Homeland Security replace BioWatch Generation 1 and 2 detectors within five years with the systems developed per action item 31a of our report. If they cannot be replaced within that timeframe, we recommend the Secretary of Homeland Security evaluate whether or not they should still be in service. Congress should require that the Department of Homeland Security and any other federal agencies that deploy biotetection systems: 1) measure and evaluate performance on a periodic basis; 2) make good faith efforts to obtain evaluative feedback from state, local, and other hosts for their systems; 3) use resulting data to improve upon current and inform future systems; and 4) provide these data and analysis to Congress for its use in oversight. If the responsible departments do not obtain these data, conduct analyses, use those analyses to optimize biotetection and

biosurveillance performance and inform procurements, and report data and analyses to Congress, Congress should no longer provide funding for, and responsible federal departments and agencies should no longer maintain, these programs.

The Honorable Michael C. Burgess, M.D.

1. Are there any strategies the Blue Ribbon panel considered regarding the availability of diagnostic testing to achieve rapid local response as well as surveillance? Has the Panel explored the role of diagnostics in outbreaks?

The Blue Ribbon Study Panel dedicated an entire meeting to discussing surveillance and detection issues in some depth. The meeting, on March 12, 2015, consisted of five panels with 19 speakers that included a former CDC Director, former Chief Medical Officer from the U.S. Department of Homeland Security, state laboratory directors, public health professionals, industry representatives, and many others.

The Blue Ribbon Study Panel recognizes that diagnostic tests play a critical role in the detection of and response to an outbreak. Our report notes that availability of point-of-care diagnostic testing would have significantly improved management of the Ebola outbreak last year. Without point-of-care testing, screening of suspected patients was often based on little more than thermometer readings and a series of questions. Diagnostics would have significantly improved quarantine and isolation decisions at home and abroad, and offered information that would have spared treatments when they are not needed. Diagnostic testing is a valuable tool to help responders establish situational awareness, screen and triage patients who have been exposed, and determine appropriate intervention strategies.

The Panel assessed that the technologies needed for the quick patient-side diagnostics of the kind used in doctors' offices to screen for influenza exist or are in development in the private sector. However, the U.S. government has not been prioritizing or adequately incentivizing the development of these technologies to maturity. Without rapid point-of-care diagnostics, the Nation remains vulnerable to biological threats. In Recommendation 30 of our report, the Panel recommends that the government develop requirements for rapid point-of-care diagnostics for all material biological threats and emerging infectious diseases. The Director of the Biomedical Advanced Research and Development Authority should determine the suite of rapid diagnostics that are needed, prioritize their development and acquisition, and implement a plan to work with industry and academia to achieve success in meeting its requirements.

2. In 2009 during the H1N1 flu epidemic, as soon as the genetic sequence of the virus was identified, hospital and public health labs were able to rapidly develop laboratory procedures to test patients suspected of having the flu. While the FDA does have the ability to issue an emergency use authorization for commercially manufactured test kits, it is laboratory developed testing procedures that provide necessary and timely local testing. You may be aware

that the FDA intends to finalize guidance requiring premarket review for all laboratory developed testing procedures. I'm concerned that these proposed changes to FDA policy could hinder the development of these diagnostics and create regulatory challenges in these situations when time is of the essence. What recommendations do you have for the FDA on how to ensure that hospital labs are able to mobilize quickly to provide diagnostics for outbreaks such as the Zika virus and other even more pathogenic infectious diseases?

Hospital and other laboratories (e.g., public health laboratories) develop and use assays to test clinical samples for pathogens of serious public health concern; as a result, they play a critical role in our ability to quickly assess and respond to emergent epidemics like that caused by Zika. In my role as President and CEO of the Biotechnology Innovation Organization (BIO), I have worked with companies developing a range of diagnostic products. Any FDA regulatory pathway designed to expedite the emergency development of diagnostic tests should be clear, apply a uniform standard, and be flexible enough so that In Vitro Diagnostic (IVD) test kit manufacturers, independent laboratories, and academic medical centers alike are able to leverage the mechanism in response to disease outbreaks. BIO welcomes the opportunity to work with the FDA to assist the Agency in developing a streamlined and efficient approach to regulating these types of emergency use tests. The FDA should continue to incorporate stakeholder feedback when developing regulatory policies for these tests and consider practical approaches that maximize the ability for diagnostic test developers to comply to ensure availability of these important products during times of emergency.

- 3. In the opening statement you mentioned that the medical countermeasures market is small, and lacks market incentives for investment. You also mentioned that the current regulatory pathways that exist for emerging infectious diseases can be unclear, which results in low innovation in the space. Aside from necessary appropriations from the BioShield Special Reserve Fund, what are some additional recommendations you or the panel could make to spur innovation in medical countermeasures?**

As we state on page 55 of our report, the best way to incentivize industry to a level that allows it to participate in biodefense programs and pursue truly innovative ideas is to: 1) fund MCM development to legislatively authorized levels; 2) re-establish multiyear advanced appropriations through the [BioShield Special Reserve Fund]; and 3) eliminate unnecessary red tape within the partnership. To further enhance the environment for innovation, especially as the partnership model between government and industry evolves, many have urged Congress and BARDA to adopt other incentives that would invigorate MCM developers.

The Panel calls upon the ASPR and DASD for Chemical and Biological Defense to convene non-governmental stakeholders to identify meaningful incentives that are independent of Congressional appropriations for MCM developers and manufacturers. Among the incentives that should be explored are success-based milestone payments and monetary prizes; minimum

procurements/advanced market commitments; guaranteed pricing; patent extensions; orphan drug status expansions; wild-card exclusivity; transferable data exclusivity extensions; and priority review vouchers (PRVs).

Several of these recommendations are addressed in existing legislation. H.R. 3299, the Strengthening Public Health Emergency Response Act (*Senate companion is S. 2055, the Medical Countermeasure Innovation Act*), introduced by Representatives Susan Brooks and Anna Eshoo, includes provisions to streamline contracting processes, coordinate stockpiling plans, and increase transparency around future MCM funding needs. The bill also provides a meaningful incentive for medical countermeasure development by extending the neglected tropical disease PRV program to the 13 deadly pathogens identified by the Department of Homeland Security as material threats to U.S. national security.

The PRV is a proven and valuable incentive that has helped to spur investment in other complex and neglected areas of R&D. Congress has recognized this and recently acted to pass a bipartisan bill adding Zika to the PRV program in an effort to encourage the private sector to prioritize and expedite the development of drugs and vaccines to treat and prevent Zika. An extension of the PRV program to include material treats is viewed by many as a way to offset the dramatic decline in federal procurement funding for MCMs. Adding MCM targets to the PRV program may help convince investors that the government is committed to this endeavor and provide increased certainty that MCMs can have value in the marketplace.

Our report calls for a revolution in the U.S. approach to the development of medical countermeasures for emerging infectious diseases with pandemic potential. BARDA, NIAID, and DOD should establish a joint program to rapidly develop MCMs as the need arises. The recent experience with Ebola showed us that rapid mobilization of government resources and private sector ingenuity could significantly shorten the amount of time needed to develop viable countermeasure candidates. We must glean lessons learned from this experience that could be applied to a new development and manufacturing paradigm. Establishment of an antigen bank as described on Page 54 of our report could help operationalize a plug-and-play strategy using proven platform technologies for use in an emergency for both human and animal pathogens.

The Panel's broader recommendations for improving the biodefense enterprise, such as institutionalizing leadership for biodefense in the Office of the Vice President, development of a comprehensive national biodefense strategy, and a unified budget, would also provide more stability, transparency, and certainty to companies looking to invest in MCMs. When companies know that the government is a committed partner in this endeavor, investment and innovation will likely increase.

As we state on pages 52 of our report, "The Nation remains unprepared for known, unknown, and unexpected threats." To address these threats, the federal government should work closely with industry to develop new strategies

that strike the right balance between stockpiling MCMs against known high consequence/low probability threats, and surge manufacturing for emerging and unknown threats. Due to the limited market for these products, federal funding for the Special Reserve Fund, BARDA, and pandemic influenza programs is extremely critical to maintaining an environment conducive to MCM innovation, and it remains the most important incentive the federal government can provide. The current shortfall we are facing for the Special Reserve Fund risks leaving critical products unfinished, and puts the nation in danger of losing the important progress we have made to date.

- 4. As a physician, I understand that the development and validation of precise diagnostics for emerging outbreaks is crucial to combating biological threats such as Zika virus. We need to quickly develop diagnostics for these purposes and work to ensure that public health laboratories and hospital laboratories throughout the country are able to screen people for the disease and that patients have access to these tests. I'm concerned that the CDC is creating barriers for laboratories to quickly disseminate the test and by not enabling competing tests, there's no way to assess whether or not the CDC test is adequate. Please describe the process CDC engages in for sharing necessary information, test reagents, and reference materials to laboratories to develop tests for emerging infectious diseases. I've also heard that despite the lack of cooperation from the CDC, some physicians have already developed tests for Zika virus at Texas Children's Hospital and Stanford University. Have you considered collaborating with these academic medical centers on developing diagnostics?**

While our Study Panel is aware of the CDC process for sharing information, test reagents, and reference materials with laboratories for the purposes of developing tests for emerging infectious diseases, we do not possess sufficient information with which to describe this process in detail for you. We recommend that you obtain this information directly from the CDC.

I can offer some additional insight from my role as the President and CEO of the Biotechnology Innovation Organization (BIO). BIO itself, an industry trade organization, has not entered into any collaborations with academic medical centers to develop diagnostics. However, many of our member companies have entered into various collaborations with academic medical centers, state and federal governments, non-governmental organizations (NGO), and other organizations and agencies to develop medical countermeasures to respond to emerging infectious diseases, pandemic influenza, and material threats and they will continue to do so in the future.

In a 2015 BIO report titled, "Advancing Translational Research for Biomedical Innovation," we highlighted that industry direct funding for university biomedical-related research stands at 49% of all industry-funded university research in 2013, reaching \$1.73 billion or just over 5% of total university biomedical-related research. Industry is relying more and more on academic research for technological development and the launch of new products. This is evident by a sharp rise in the share of patents associated with new therapies

citing academic research over the past decade. Industry-university research collaborations continue to evolve and BIO will play in critical role in bridging the worlds of biotechnology industry and academic research.

The Honorable Susan Brooks

1. Your testimony notes the past effectiveness of priority review vouchers (PRVs) in incentivizing research. Please identify existing PRV programs for rare pediatric diseases and neglected tropical diseases, and share your assessment of any related increases in biotech investments in these areas. (Question for the Record and Member Request for the Record)

Priority review vouchers provide a powerful incentive to stimulate drug development in complex and underserved diseases or conditions. The current programs focus on neglected tropical diseases (NTDs) and rare pediatric diseases which, like medical countermeasures, often lack the market opportunity to attract significant investment. The priority review voucher is awarded to a company when a new product for a qualifying disease is approved. The company may use the voucher to expedite the review of another product by 4 months or they may sell the voucher to another company. Recent sale prices for priority review vouchers demonstrate the significant value of this incentive to manufacturers.

To date, nine priority review vouchers have been awarded – three through the neglected tropical disease program and six through the rare pediatric disease program. A chart summarizing these awards is included below.

| Year | Disease | Drug | Company | Program |
|-------------|--|-----------------------------------|---------------------|----------------|
| 2009 | Malaria | Coartem (artemether/lumefantrine) | Novartis | NTD |
| 2012 | Tuberculosis | Sirturo (bedaquiline) | Janssen (J&J) | NTD |
| 2014 | Morquio A syndrome | Vimizim (elosulfase alfa) | BioMarin | Rare pediatric |
| 2014 | Leishmaniasis | Impavido (miltefosine) | Knight | NTD |
| 2015 | High-risk neuroblastoma | Unituxin (dinutuximab) | United Therapeutics | Rare pediatric |
| 2015 | Rare bile acid synthesis disorders | Cholbam | Asklepiion | Rare pediatric |
| 2015 | Hereditary orotic aciduria | Xuriden | Wellstat | Rare pediatric |
| 2015 | Hypophosphatasia | Strensiq (asfotase alfa) | Alexion | Rare pediatric |
| 2015 | Lysosomal acid lipase (LAL) deficiency | Kanuma (sebelipase alfa) | Alexion | Rare pediatric |

BIO believes that these programs, and the neglected tropical disease priority review program in particular, have been successful in stimulating new drug

development in these critical areas of unmet medical need. In evaluating the impact of these programs on investment in the areas of neglected tropical disease and rare pediatric disease, however, the available data are not sufficiently granular to identify investment in rare pediatric disease and neglected tropical disease from broader categories of biopharmaceutical investment.

Using the number of clinical development programs as a proxy for overall investment in neglected tropical diseases, we have seen an increase in research and development pipeline activity and, therefore, investment in the area of neglected tropical diseases. At present, there are at least 43 clinical development programs focused on the eligible neglected tropical diseases, including 13 for Malaria, 12 for Tuberculosis, and 10 for Ebolavirus. This is supported by the larger overall trend observed in venture (private company) investment in infectious disease, which has seen a 220% increase between 2012 and 2015, and is presumed to include a significant increase in investment in neglected tropical diseases.

Regarding pediatric rare diseases, as a recent GAO study noted, it is still "too early to gauge the effectiveness" of the rare pediatric disease priority review voucher program. The rare pediatric disease voucher program was created in 2012 with the passage of the Food and Drug Administration Safety and Innovation Act (FDASIA). Unlike the neglected tropical disease voucher program, which is permanent, the authority of the Secretary to award vouchers was set to terminate one year after the award of the third voucher under this program (which was awarded in March 2015). Though the program received an extension through September 2016 in last year's Omnibus package, the unclear future of the program and lack of permanence introduces significant uncertainty and unpredictability for sponsors who are considering the risky, long, and costly investment into a clinical development program for rare pediatric condition. For this reason, BIO has supported and continues to work with Congress to make the program permanent, so the full potential of the program can be realized in stimulating new drug development of new therapies for devastating childhood diseases.

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April 5, 2016

Dr. Tara O'Toole, M.D., M.P.H.
Senior Fellow
IQT
2107 Wilson Boulevard, Suite 1100
Arlington, VA 22201

Dear Dr. O'Toole:


Thank you for appearing before the Subcommittee on Oversight and Investigations on Friday, February 12, 2016, to testify at the hearing entitled "Outbreaks, Attacks, and Accidents: Combatting Biological Threats."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

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Sincerely,



Tim Murphy
Chairman

Subcommittee on Oversight and Investigations

cc: The Honorable Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Attachment

To: Subcommittee on Oversight and Investigations, February 12, 2016

“Outbreaks, Attacks and Accidents: Combatting Biological Threats

Question from:

The Honorable Michael C. Burgess, MD

1. As a physician, I understand that the development and validation of precise diagnostics for emerging outbreaks is crucial to combating biological threats such as Zika virus. We need to quickly develop diagnostics for these purposes and work to ensure that public health laboratories and hospital laboratories throughout the country are able to screen people for the disease and that patients have access to these tests. I’m concerned that the CDC is creating barriers for laboratories to quickly disseminate the test and by not enabling competing tests, there’s no way to assess whether or not the CDC test is adequate. Please describe the process CDC engages in for sharing necessary information, test reagents, and reference materials to laboratories to develop tests for emerging infectious diseases. I’ve also heard that despite the lack of cooperation from the CDC, some physicians have already developed tests for Zika virus at Texas Children’s Hospital and Stanford University. Have you considered collaborating with these academic medical centers on developing diagnostics?

ANSWER:

Thank you for the question, Congressman. Accurate diagnostic tests are essential tools for rapidly identifying and quenching epidemics of infectious disease. The strategic importance of diagnostic tests is not well recognized, and not reflected in government funding for infectious disease, and there are multiple, significant market issues which discourage the private sector from developing diagnostics for infectious disease, in spite of a wealth of technologies which could be utilized. Some of these impediments include regulatory hurdles – particularly regulatory uncertainty; poor return on investment for diagnostics compared to therapeutics; significant hurdles associated with getting new tests approved for payment by layers of insurers; and even hospital resistance to using new tests because billing practices are “locked-in” to electronic health records and difficult to change.

I am not familiar with the details of CDC’s efforts to develop and disseminate diagnostic tests for Zika virus. Typically, CDC – which is, at heart, a reference laboratory – seeks to develop highly accurate tests that serve as the standard for all other tests and then disseminates the procedures and reagents for conducting such tests to state public health labs and other reference laboratories around the country. It takes time to develop and validate such tests and to procure and distribute the necessary instructions, reagents, etc. These tests may diffuse into clinical care settings or other test processes may be developed by diagnostic companies, achieve FDA approval and become the usual method of diagnosis in clinical labs because they are deemed sufficiently accurate and seen as cheaper, easier, faster, etc.

Sophisticated clinical laboratories, including for-profit labs and many hospital labs, have sometimes developed their own diagnostic tests, to provide faster results, reduce costs or to address specific clinical questions. Over time, the number of such tests has grown. This is not necessarily a bad development, but it does make it difficult to compare the results of different tests across institutions.

As I know you recognize, Congressman, the usefulness and performance characteristics of a diagnostic test, known as the Positive Predictive Value (PPV), varies depending on the “use case” and setting in which it is employed. The PPV of a test measures the percentage of the time a test accurately reports a “positive” result when the infection or condition of interest is actually present. PPV, and its counterpart, the Negative Predictive Value (the percent of time a Negative test result accurately reports that the infection being tested for is truly not present), are measures of the sensitivity and specificity of the test and the prevalence of the disease or condition in the population being tested.

The dilemma with Zika virus is that CDC – and the country – have a legitimate and pressing interest in ensuring that the reference diagnostic tests in use are accurate and reliable. Meanwhile, patients and their physicians are desperate for a diagnosis and clamoring for an acceptable diagnostic in the absence of a commercially available test, thus putting pressure on hospitals to develop their own methods. Different tests being developed by different hospitals, without careful standardization and comparison, guarantees differences in performance – i.e. differences in False Positive, False Negative results from test to test. Without an understanding of how “bespoke” tests compare to a “gold standard”, clinicians cannot make informed judgments of test results, and CDC will be unable to assemble a clear picture of the incidence or prevalence of Zika in the population. The stakes on both sides are quite high, but in the long term, it is clearly in the public interest to have a reliable reference diagnostic as well as other diagnostic tests designed for specific use cases.

In-Q-Tel is not in a position to develop diagnostic tests, but as part of our BiologyNext Initiative, we are examining new diagnostic technologies – especially how new tools might enable the rapid design and manufacture of cheap diagnostics that deliver results within an hour – and market issues associated with private sector development. One can imagine the West Africa Ebola outbreak might have been controlled faster and with fewer victims had we had such diagnostic tools at hand or were able to develop them quickly. Thank you for noting the efforts at Stanford and Texas Children’s Hospital to develop Zika diagnoses. My colleagues and I are interested in learning more about their work and will pursue.

It is important to recognize that diagnostic tests for infectious disease are **strategically** important to attempts to achieve early recognition and containment of disease outbreaks. Without clear diagnostic confirmation of cases, decision makers almost always delay action until a large number of cases have accumulated, erasing any doubt of an outbreak – and by then, the challenge of quenching the outbreak is more challenging. Lots of effective diagnostic technologies are available, some offering rapid read-outs. Major impediments to developing such tests include regulatory uncertainty, the difficulty of obtaining curated samples of the infectious agent in question to validate tests, poor return on investment due to billing practices, and the US government’s failure to recognize the importance of and provide support for (e.g. through BARDA) rapid, reliable clinical diagnostic tests that could be used at point-of –care.

Submitted by: Tara O’Toole, MD, MPH

April 11, 2016

FRED UPTON, MICHIGAN
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

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April 5, 2016

Dr. Gerald W. Parker, D.V.M., Ph.D.
Associate Vice President, Public Health Preparedness and Response
The Texas A&M University System
1747 Pennsylvania Avenue, N.W., Suite 400
Washington, DC 20006

Dear Dr. Parker:


Thank you for appearing before the Subcommittee on Oversight and Investigations on Friday, February 12, 2016, to testify at the hearing entitled "Outbreaks, Attacks, and Accidents: Combatting Biological Threats."

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Sincerely,



Tim Murphy
Chairman

Subcommittee on Oversight and Investigations

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Attachment

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U.S. House Committee on Energy and Commerce
Subcommittee on Oversight and Investigations hearing on Friday, February 12, 2016 entitled "Outbreaks, Attacks, and Accidents: Combatting Biological Threats."

The Honorable Michael C. Burgess, M.D. (TX – 26)

As a physician, I understand that the development and validation of precise diagnostics for emerging outbreaks is crucial to combating biological threats such as Zika virus. We need to quickly develop diagnostics for these purposes and work to ensure that public health laboratories and hospital laboratories throughout the country are able to screen people for the disease and that patients have access to these tests. I'm concerned that the CDC is creating barriers for laboratories to quickly disseminate the test and by not enabling competing tests, there's no way to assess whether or not the CDC test is adequate. Please describe the process CDC engages in for sharing necessary information, test reagents, and reference materials to laboratories to develop tests for emerging infectious diseases. I've also heard that despite the lack of cooperation from the CDC, some physicians have already developed tests for Zika virus at Texas Children's Hospital and Stanford University. Have you considered collaborating with these academic medical centers on developing diagnostics?

Response to the Additional Question for the Record

The importance of near-real time biosurveillance, laboratory capacity and accurate point of need diagnostics for emerging and reemerging infectious diseases, as well as biodefense cannot be overstated. Development efforts for rapid detection/diagnostics, whether from natural outbreaks or deliberate attacks have not been given sufficient long-term attention and programmatic priority.

I hope you can see from this statement that I share your understanding and concern that we urgently need more development programs now for accurate and rapid Zika point of care diagnostics for patients in the health care setting. But we also need long-term, sustainable and focused rapid detection/diagnostic programs for emerging infectious diseases not only for patients, but also in a broader one health context that encompasses the human/animal nexus because most emerging infectious diseases that we have experienced, and can expect to see in the future are zoonotic. The gaps and funding shortfalls in veterinary diagnostic laboratory capabilities and capacities are much worse compared to the gaps in the CDC laboratory response network and need to be addressed too.

The unfolding Zika outbreak is serious, and once again highlights the importance of rapid and accurate diagnostics. There are no FDA approved Zika diagnostics available, but the CDC is gearing up and working hard to respond to this serious crisis to support state and local public health authorities. I cannot speak on behalf of the CDC regarding their laboratory testing procedures, so it is recommended that the committee ask the CDC directly how they are making information, testing materials and test results

available to laboratories and health care providers. But, I will summarize what I understand from publically available information, personal experiences and interaction with public health colleagues on how CDC is supporting local and state health authorities, as well as clinicians and their patients regarding Zika diagnostics.

Zika virus is a nationally notifiable disease. State, local and territorial health departments are encouraged to report laboratory-confirmed cases of any arbovirus, such as Zika, to CDC through ArboNET, the national surveillance system for arboviral diseases. Healthcare providers should report suspected Zika cases to their local, state or territorial health department according to laws or regulations for reportable diseases in their jurisdiction. Clinicians should consult with, and obtain information for submitting clinical samples for Zika testing from their health department of jurisdiction.

The CDC has developed two diagnostic tools; 1) the CDC Zika IgM Capture Enzyme-Linked Immunosorbent Assay (ZIKA MAC-ELISA) to detect antibodies the body makes in response to an infection that may indicate a recent Zika and/or related arbovirus infection such as Dengue, and 2) the Trioplex Real-time Reverse Transcription Polymerase Chain Reaction (Trioplex rRT-PCR) assay to detect the presence of Zika, Chikungunya or Dengue genetic material to determine which infection a patient may have.

The CDC requested, and the FDA recently issued an Emergency Use Authorization (EUA) for these two CDC diagnostic tests. The CDC will distribute these tools and reagents to qualified laboratories in the laboratory response network, but only those labs certified by the CDC to perform high-complexity tests. Test results require careful interpretation, and CDC provides laboratories, health care providers and tested individuals with information regarding these Zika laboratory diagnostics, to include limitations of the tests and guidance for interpretation of test results in the context of a patient's travel history, clinical history and other epidemiologic criteria. There is no indication that CDC plans to distribute these diagnostic tools to hospitals or other health care settings, but rather limit their availability to a relatively few specialized CDC approved public health laboratories.

Clinicians must submit samples for testing to their local or state public health department of jurisdiction, and not to CDC directly. Test results will be reported back to the state or local health departments of jurisdiction, not directly to clinicians. CDC's website indicates laboratory results are currently taking at least 3 weeks to report after receipt of a sample, and that health departments, clinicians and patients should expect longer reporting delays as summer approaches.

Clinicians and patients alike urgently need point of care Zika diagnostics that provide rapid, accurate results. Advanced diagnostics being developed by hospitals, academia and industry, such as the Texas Children's and Houston Methodist Hospital collaborative in Texas are very encouraging. My colleagues and I at Texas A&M University will promote and collaborate with Texas Children's and Houston Methodist Hospital, as well as other institutions in Texas and globally on emerging infectious disease diagnostics and biosurveillance systems, to include Zika diagnostics. I have been in direct contact with the Texas Children's Hospital collaborative as well as a similar effort at UTMB through Governor Abbot's Texas Task Force on Emerging Infectious Disease Preparedness. It is clear that Zika testing demands will outpace CDC approved laboratory capacity, if it has not done so already as CDC laboratory reporting already requires at least 3 weeks. Hospital-based diagnostics offer the potential to provide test results in hours, not weeks; and to overcome a public health laboratory capacity bottleneck. Hospital-

based local testing also enables rapid, direct and local clinician to clinical laboratory pathology consultation further improving patient outcomes. However, with any new diagnostic technology that is not yet FDA approved, use in a clinical setting must be done in strict compliance with clinical laboratory standards and regulations.

